



P2131

AUTOMATED FIELD STEAM STERILIZER

NSN: 6530-01-641-4641

TECHNICAL MANUAL



Fort Defiance Industries LLC (FDI)
2411 Maremont Pkwy · Loudon, TN · 37774
Phone: (865) 408-0100 · techsupport@fortdefianceind.com

The P2131 Automated Field Steam Sterilizer complies with the applicable requirements of the following standards:

- ANSI/AAMI ST8:2013, *Hospital Steam Sterilizers*
- UL 61010-1 2nd Edition, *Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use – Part 1 General Requirements*
- IEC 61010-2-040 1st Edition, *Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*
- ASME Boiler and Pressure Vessel Code, Section VIII, Division I, Current Edition, *Rules for Construction of Pressure Vessels*



Fort Defiance Industries (FDI) is ISO 13485:2016 certified and Food and Drug Administration compliant for the design and manufacture of sterilizers for the medical device industry.



Fort Defiance Industries LLC
Certified to ISO 13485:2016
ISO Certificate #: US19/819943310
MDSAP: United States, Canada
MDSAP Certificate #: US19/81841407

Continual Improvement

Fort Defiance Industries LLC (FDI) is committed to providing our customers with a safe and effective product that is simple and easy to operate and maintain. As an ISO 13485:2016 certified company, we have a strong desire to continually improve. If you have any feedback regarding the P2131 sterilizer or this technical manual, please contact us. If any critical updates to the P2131 Sterilizer become necessary, the updates will be communicated through a Medical Device Advisory Notice. It is imperative that these notices be read in full and followed.

FEEDBACK FOR IMPROVEMENT AND GENERAL QUESTIONS

Fort Defiance Industries LLC

2411 Maremont Pkwy

Loudon, TN 37774

techsupport@fortdefianceind.com

865-408-0100 [phone] fortdefianceind.com

Operational and Maintenance Videos

Please visit the FDI video channel for helpful and informative videos on the operation and maintenance of the P2131 Automated Field Steam Sterilizer. Scan the QR code below, click on the hyperlink (if you are using the electronic version of the manual), or enter the Web address listed to access these videos.

NOTE: This channel is updated as new material is produced, so check back periodically to view new content.



<https://tinyurl.com/2kraxrf9>

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COMPACT DISC TABLE OF CONTENTS

The following files can be found on the CD that accompanies this technical manual.

<u>ITEM</u>	<u>FILE NAME</u>
1.	Technical Manual – P2131 Automated Field Steam Sterilizer
2.	An Installer’s Pocket Guide for Swagelok Tube Fittings
3.	Programmable Logic Controller (PLC) Manual

LIST OF ACRONYMS

<u>ACRONYM</u>	<u>DEFINITION</u>
AAMI	Association for the Advancement of Medical Instrumentation
AFS	Automated Field Steam Sterilizer
ASME	American Society of Mechanical Engineers
BI	Biological indicator
B&PV	Boiler and Pressure Vessel
CI	Chemical integrator
DI	Deionized
FDA	Food and Drug Administration
FDI	Fort Defiance Industries LLC
IFU	Instructions for Use
HTS	High Temperature Limit Switch
IQ/OQ/PQ	Installation, Operational, and Performance Qualification
IUSS	Immediate Use Steam Sterilization
MAWP	Maximum Allowable Working Pressure
MTTR	Mean-time-to-repair
PCD	Process challenge device
PLC	Programmable logic controller
PSV	Pressure safety valve
RTD	Resistance temperature detector
SAB	Sterilizer Accessory Bag
SMU	Sterilizer Main Unit
SWS	Sterilizer Water Softener
TDS	Total Dissolved Solids
WRS	Water Recovery System

SECTION 1 – INTRODUCTION

1.1 Safety Precautions

WARNINGS

This manual contains critical information on the proper use of the Automated Field Steam Sterilizer (P2131 sterilizer). All operators and maintainers of this sterilizer must be properly trained prior to operation or service and are urged to carefully read this manual in its entirety to become familiar with the warnings, cautions, and instructions for use.

- This sterilizer is equipped with a High Temperature Limit Switch. Should the heaters be energized in a low or no water condition, this switch will protect the chamber and other components by switching off power to the PLC and the Heater Contactor. This alarm condition is identified by a sustained audible tone.
- Regularly scheduled preventive maintenance is required for the safe and reliable operation of the P2131 sterilizer. Reference Section 4 for details.
- Service and maintenance work must be performed by qualified personnel only.
- Repair parts must be authorized for use in the P2131 sterilizer and should be sourced from FDI. Use of unauthorized parts could compromise the safety and/or efficacy of the sterilizer and will void the warranty.
- **Burn hazard:**
 - Chamber door and rack/shelves will be hot after a cycle. Always wear protective gloves and apron when loading and unloading the chamber.
 - Hot water can remain in the chamber after a cycle. Always wear protective gloves.
 - Before performing any cleaning or maintenance, allow sterilizer to cool to ambient temperature.
 - Hot steam can flow out of the chamber when the door is opened. Keep a safe distance from the door and open the door slowly to reduce steam exposure. Always wear protective gloves.
 - Water Recovery System (WRS) Left Side Panel will be hot during and after cycles. Do not touch the panel or perform maintenance on the WRS until the panel has cooled.
- **Electrical shock and burn hazard:** Do not service unless the sterilizer has been de-energized per the appropriate safety-related work practice standards.
- **Explosion hazard:** Do not process flammable materials in this sterilizer. Only medical supplies and materials per the intended use as described in Section 2.1 should be processed.

WARNINGS

- **Slipping hazard:** Ensure that any water leaks or spills are immediately wiped up.
- **Trip hazard:** Carefully organize the layout of the incoming power and water lines for safety.
- The sterilizer has a pressure vessel that has been ASME B&PV code stamped. It is a violation of federal code to replace the main door plate or make any weld repairs to the pressure vessel. All repairs to the pressure vessel, including the door plate, must be made by FDI.
- Sterility could be compromised if Bowie-Dick, vacuum-leak, or biological indicator testing indicates a problem. Refer any concern to a qualified equipment technician before continuing to use the sterilizer.
- Do not re-use biological indicators (BIs), chemical integrators (CIs) or Bowie-Dick Test Packs. Check the expiration date before use.
- Sterility could be compromised if Association for the Advancement of Medical Instrumentation (AAMI) guidelines are not followed for cleaning, decontaminating, packaging, and preparing prior to sterilization. In addition, it is critical for the user to follow AAMI guidelines to conduct routine biological monitoring to verify the sterilization performance.
- Refer to the instrument device manufacturer's Instructions for Use (IFU) before selecting the appropriate cycle, including exposure and dry times.
- The P2131 sterilizer is designed to sterilize loads using only the FDA-cleared cycles as specified in this manual. If you have any question or concern about a specific material, instrument, or device, contact the manufacturer of the device to obtain the specific IFU.
- The P2131 sterilizer does not include a sterilization cycle for liquids. **DO NOT ATTEMPT TO STERILIZE ANY LIQUIDS IN THIS STERILIZER.**
- After transport and relocation, the installation must include proper Installation, Operational, and Performance Qualification (IQ/OQ/PQ) testing per AAMI standards. Reference Section 3.1.
- Do not use compressed air to hasten the draining or drying process as the high pressure could damage the pressure vessel (40 psig MAWP), WRS water tank, or instrumentation.
- Do not remove orange-colored insulation sleeves that are used throughout the sterilizer. The insulation sleeves protect the user from potential burns and ensure correct performance of the Sterilizer. Replace if it becomes damaged and/or lost during maintenance.

SECTION 2 – GENERAL INFORMATION

2.1 Intended Use and System Design

The P2131 sterilizer is designed for sterilization of porous and nonporous and heat- and moisture-stable materials (e.g., surgical instruments and textiles) used in healthcare facilities. The P2131 sterilizer is a rugged, transportable device designed for field use in a variety of austere environments. Ambient operating conditions include sea level to 8,000 feet altitude and 40°F to 130°F.

The P2131 sterilizer is a pre-vacuum and post-vacuum sterilizer that has a conditioning stage with vacuum air removal before the start of the exposure stage, as well as a post-exposure drying stage that is based on the combined operation of heat and vacuum. The sterilization agent is steam that is electrically generated in a jacketed boiler.

The P2131 sterilizer consists of three components that work together as one integrated system. These components are the (1) Sterilizer Main Unit (SMU), (2) Water Recovery System (WRS), and (3) Sterilizer Water Softener (SWS). The WRS reclaims hot condensate and exhaust steam for re-use by the SMU. The WRS also includes a water eductor, which provides the vacuum capability for the pre and post-vac phases of sterilization. The SWS deionizes the incoming water to prevent scale buildup and reduce the effects of water on the metal components. A manual hand pump is also provided with the SWS to pull water from a Jerry can or bucket if a pressurized water system is not available.

The P2131 sterilizer is an automated, microprocessor-controlled, pre-vacuum autoclave. A visual alert indicator (LED light) and an audible alarm notify the operator of any abnormal condition during operation. It has a fully jacketed, horizontal-type pressure vessel and is designed as a transportable sterilization unit. The P2131 sterilizer is of welded-aluminum alloy construction to minimize weight. The chamber assembly, with internal dimensions of 16" diameter x 36" long, is supported in a combination frame and endcap assembly to provide rigidity and protection. The endcaps, when closed, completely enclose and protect the sterilizer and provide the capability to serve as a shipping container. When the endcaps are opened, they provide an integral stand, placing the sterilizing chamber and operating controls at a convenient working height.

Universal shelves are supplied to provide three shelf levels, the top two in any combination to provide flexibility. The shelves are removable and stack for compact storage. The sterilizer is designed to use the jacket as a steam boiler. Electric immersion heaters boil the water and produce steam. Water is retained in the jacket of the sterilizer, and when it is heated, the steam is directed through a solenoid valve and tubing into the chamber. A baffle disperses the steam as it enters the chamber. A water level sight glass is located at the rear of the SMU. A low-water cutoff switch is provided for protection of the electric heating elements. In addition, as a

secondary safeguard, the unit is equipped with a High Temperature Limit Switch to turn off power to the heaters and PLC. Hot condensate exits the SMU to the WRS through a chamber drain screen, drain manifold, and hose. Air and steam can exhaust rapidly to the WRS through the same drain manifold via hoses and the vacuum/exhaust solenoid valve. The WRS sits underneath the SMU and has three main purposes: (1) to capture exhaust steam and condensate, thus creating a closed-loop system to reclaim nearly all the water used during sterilization, (2) to cool and then pump the recovered water back to the boiler for reuse, and (3) to generate vacuum through a water eductor for the pre- and post-vac phases of operation.

2.2 Specifications and Physical Data

Sterilizer Main Unit (SMU):

• Electrical ratings	208-230 VAC, 3 phase, 30 amps, 50/60 Hz
• Sterilizing temperature	270°F (132°C)
• Pre-vacuum phase	3 pressure/vacuum pulses
• Maximum working pressure/vacuum	40 psig/full vacuum
• Electrical receptacle	MIL-C-22992 cord connecting class L
• Length (endcaps closed for transport)	46.00"
• Length (endcaps open for operation)	38.00"
• Width	26.75"
• Height (endcaps closed for transport)	31.00"
• Height (endcaps open for operation)	62.00"
• Chamber size	16" diam x 36" long (4.2 ft ³)
• SMU weight (dry)	306 lbs.
• SAB weight	17 lbs.
• Jacket (boiler) water capacity	4.25 gallons
• NEMA Classification ¹	2 – dry Location
• Operating altitude	0 – 8,000 feet
• Operating ambient temperature	40°F – 130°F

Water Recovery System (WRS):

• Length x Width x Height	30" x 23.75" x 24.5"
• Weight (dry, S/N's: AFS-0001 - 0236)	170 lbs.
• Weight (dry, S/N's after AFS-0236)	151 lbs.
• Water capacity	6 gallons
• Vacuum eductor capacity	25" Hg.
• Electrical ratings	115 VAC, 1 phase (supplied from SMU)
• Sound level	78 dBA
• NEMA Classification ¹	2 – dry location

Sterilizer Water Softener (SWS):

• Length x Width x Height	15" x 15" x 38.75"
• Weight (dry)	35 lbs.
• Electrical Power	N/A

¹NEMA 2. Designed for operation in dry location. Protection provided from falling dirt and water during transport/storage.

2.3 Sterilization Cycles – FDA Cleared

Cycle	Recommended Use	Maximum Load	Exposure Temperature ¹ (°F/°C)	Exposure Time (minutes)	Dry Time (minutes)
Immediate Use (IUSS)	Unwrapped nonporous (e.g., instruments) and porous items in mixed loads	36 lbs.	270/132	4	0
Textiles	Textile packs	3 textile packs ²	270/132	4	5 ³
Wrapped Instruments	Wrapped instruments/utensils	36 lbs.	270/132	4	20 ³
Wrapped Instruments	Wrapped instruments/utensils	36 lbs.	270/132	10 ⁴	20 ³
Bowie-Dick Test	Test	NA	273/134	3.5	0
Vacuum Leak Test	Test	NA	NA	Test time 20	0

¹ The AAMI minimum temperature is 270°F (132°C) for all cycles except Bowie-Dick which is 273°F (134°C). The P2131 sterilizer setpoint temperature is 273°F (134°C) for all cycles except Bowie-Dick which is 274°F.

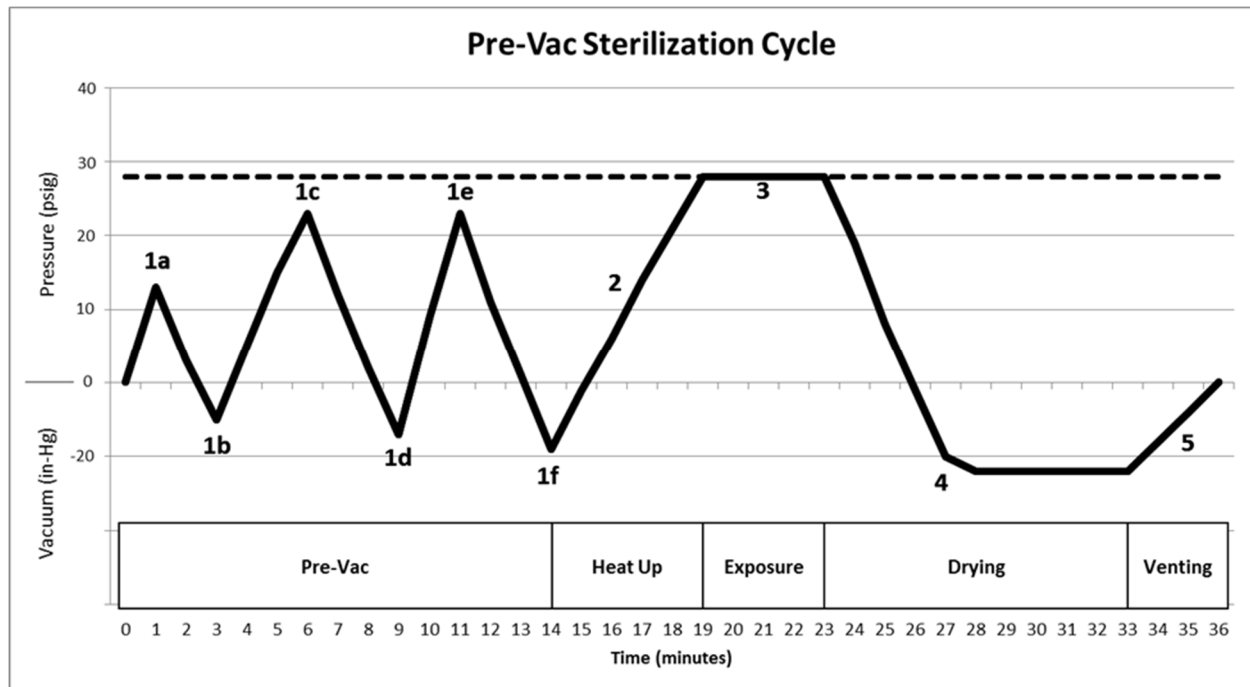
² AAMI standard 16-towel pack (9"x9"x6").

³ Dry times are pre-set to established standard conditions, but can be manually increased.

⁴ The FDA-cleared Process Challenge Device (PCD) for this 10-minute cycle can be purchased from FDI at (865) 408-0100 or via email at sales@fortdefianceind.com. Reference Appendix A.3 for additional information on this PCD.

WARNING: The P2131 sterilizer does not include a sterilization cycle for liquids. **DO NOT ATTEMPT TO STERILIZE ANY LIQUIDS.**

2.4 Description of Cycle Phases



Schematic of a Dynamic Air Removal (Pre-Vac) Cycle

Below is a description of the various phases of a P2131 sterilizer textile or wrapped instrument cycle. **NOTE:** The IUSS cycle has no dry phase.

1. Preconditioning (pre-vacuum)
 - a. Steam Flush – An initial pulse of steam is released into the chamber and flows directly out of the chamber into the WRS. This steam flush removes most of the air from the chamber.
 - b. Vacuum Pulse #1 – A medium vacuum is pulled on the chamber to remove more air.
 - c. Steam Pulse #1 – Steam is released into the chamber to increase pressure and temperature to heat up the load.
 - d. Vacuum Pulse #2 – A slightly deeper vacuum is pulled on the chamber to remove even more air.
 - e. Steam Pulse #2 – Steam is released into the chamber again to increase pressure and to continue heating up the load.
 - f. Vacuum Pulse #3 – This is the final and deepest vacuum pulse during which nearly all of the air is removed from the chamber.
2. Heatup – During this phase, steam fills the chamber to build up pressure and temperature until the exposure temperature is reached.

3. Exposure – Steam flowing into the chamber slows and the temperature sensor, PLC, and heaters begin controlling the temperature inside the chamber so that it stays within a specified range during the entire exposure time selected.

NOTE: The P2131 is controlled by temperature, not by pressure, during exposure.

4. Drying – A deep vacuum is drawn on the chamber to remove the steam and residual moisture from the sterilized items.
5. Venting – The vacuum is released by bringing in outside air through the HEPA filter so the chamber door can be opened by the operator.

2.5 Water Supply Quality

It is critical to the long-term reliability and performance of the P2131 sterilizer that only potable water (i.e., water safe for human consumption) should be used as the feedwater to the SWS. The feedwater should meet FDA bottled water criteria for total coliform (i.e., a disinfectant such as chlorine should be present). Reference Appendix A.6 for suggested maximum values of contaminants in the feed water.

The P2131 sterilizer can operate for 14 days or 100 cycles with only 10 gallons of water. However, the FDA requires that the water in the SMU and WRS must be drained and refilled every 14 days or 100 cycles (whichever comes first). Reference Section 3.4.













CAUTION: It is critical to use and maintain the SWS. Reference Sections 3.4 and 4.3.4.

If a pressurized potable water system is available, a hose can be connected directly to the inlet of the SWS. As water flows through the SWS, calcium, magnesium, and other contaminants are removed from the water, preventing deposits (i.e., scale buildup) on the heating elements, jacket walls, and other components. This deionized water will also prevent premature corrosion of the metal components. If a pressurized water system is not available, the SWS is equipped with a manual hand pump, suction hose, and inlet strainer. This will allow potable water to be manually pumped from a bucket or Jerry can through the SWS and into the WRS for use in the SMU. The three important benefits of using the SWS are:

1. Eliminates costly sterilizer downtime and maintenance labor to replace heating elements and to scrape and clean the boiler surfaces.
2. Improves sterilizer cycle times by keeping heatup times short (1.6 mm of scale buildup on the heating elements causes a 12% loss in heating efficiency).
3. Improves safety by eliminating the potential for sterilizer rupture due to localized hot spots or premature corrosion that cause weakening of the aluminum.

2.6 Sterility Assurance Products

FDI recommends either of the two options listed below to ensure successful sterilization with each load processed. Option 1 is a combination of VERIFY™ and 3M® products, and Option 2 is the 3M® line of products only.

	VERIFY™ and 3M® System	3M® System
4-Minute Exposure	 <p>Reusable Process Challenge Device P/N: P2131-1-9003</p>	 <p>1296 - Biological Process Challenge Device P/N: P2131-1-9010</p>
	 <p>Class 5 Chemical Integrator P/N: P2131-1-9004</p>	<p>OR</p>  <p>Attest™ Steam Chemical Integrator P/N: P2131-1-9011</p>
	 <p>1292 - Biological Indicator P/N: P2131-1-9012</p>	 <p>1292 - Biological Indicator P/N: P2131-1-9012</p>
10-Minute Exposure	 <p>Reusable Process Challenge Device P/N: P2131-1-9003</p>	<p>NOTE: There are currently no other FDA-Cleared PCDs for a 10-minute pre-vacuum cycle.</p>
	 <p>Extended Cycle Tube P/N: P2131-1-9005</p>	
	 <p>1292 - Biological Indicator P/N: P2131-1-9012</p>	
Bowie-Dick Test	 <p>Reusable Process Challenge Device P/N: P2131-1-9003</p>	<p>OR</p>  <p>1233L - Bowie-Dick Test Pack P/N: P2131-1-9013</p>
	 <p>Bowie Dick Test Strip P/N: P2131-1-9006</p>	

NOTE: The FDA-cleared VERIFY™ Reusable Process Challenge Device (PCD), along with other STERIS® products, can be purchased from FDI at (865) 408-0100 or via email at sales@fortdefianceind.com. Reference Appendix A.3 for additional information on this PCD.

SECTION 3 – OPERATION

The P2131 sterilizer system includes the following:

1. One SMU (P/N: P2131-1)
2. One WRS (P/N: P2131-2)
3. One SWS (P/N: P2131-3)
4. One SAB (P/N: P2131-4)



Sterilizer Accessory Bag (SAB):

The SAB is stored in the SMU chamber during transport but contains items necessary for both setup and maintenance. The items found in this bag include:

1. One Sterilizer Accessory Bag (P/N: P2131-1-7000)
2. Three SMU to WRS connection hoses
 - Recovered Water Hose (P/N: P2131-1-3101)
 - Vacuum/Exhaust Hose (P/N: P2131-1-3102)
 - Condensate Hose (P/N: P2131-1-3103)
3. One high-temperature drain hose (P/N: P2131-1-3104)
4. Six shelves (P/N: P2131-1-2002)
5. Twelve leveling shims (P/N: P2131-1-2016)
6. Handheld TDS (Total Dissolved Solids) Meter (P/N: P2131-3-9010)
7. Twenty-five spare hose fitting O-rings (P/N: P2131-1-3408)
8. One spare door O-ring gasket (color is red or black) (P/N: P2131-1-1029)
9. Three spare 30-amp fuses (P/N: P2131-1-4012) and three spare 750-milliamp fuses (P/N: P2131-1-4013) in rigid plastic container
10. One setup multi-tool for S/N's AFS-0001 through AFS-0215 (P/N: P2131-1-2020)
 - **For S/N's after AFS-0215, the multi-tool is stored in the rear endcap*
11. One Technical Manual with a digital version on CD (P/N: P2131-1-8001)
12. One MicroSD w/adaptor (P/N: P2131-1-4020) and Micro SD extender (P/N: P2131-1-4028)
13. Five spare Chamber Drain Screen O-rings (P/N: P2131-1-1150)
 - *For S/N's AFS-0001 through AFS-0203: Chamber Drain Screen is in SAB. (P/N: P2131-1-0019).*
 - **For S/N's after AFS-0203, Chamber Drain Screen is stored in chamber and snaps in with O-ring.*
14. Fifty water chlorine level test strips (P/N: P2131-3-9007)
 - *After AFS-0236, water chlorine level test strips included in SAB.*
15. One HTS-1 Test Jumper (P/N: P2131-1-4034)
16. One Spare Deionized Housing O-ring (P/N: P2131-3-9011)



3.1 INSTALLATION, SETUP, AND QUALIFICATION (IQ, OQ, PQ)

WARNING: To prevent potential injuries during transport, installation and setup, FDI recommends a six-person team lift for the SMU and a four-person team lift for the WRS.

1. The P2131 sterilizer is designed to be carried by 6 people.



2. Place the SMU on one of its ends.



3. Unlock the two latches holding the endcap against the main frame.



4. Holding securely onto the SIDES of the endcap, slowly pivot the endcap to the fully open position (do not allow endcap to drop).

WARNING: A potential pinch point exists near the hinge area of the endcap. It is very important to keep hands positioned on the SIDES of the endcap and away from the pinch point.

✗ Placing your hand near the hinge can result in injury. Keep hands positioned on the sides of the endcap and away from the pinch point.



✓ Proper hand placement is on the side of the end cap, away from the pinch point. This will help avoid injury when opening the endcap.

5. On each side, screw the black endcap knobs down securely. Ensure the endcap knobs are fully seated by checking to see if the white washer in between the knob and the spring does not spin. Do not overtighten.



6. Tilt the SMU down onto the endcap that was just opened.



7. Position one person on each side of the SMU. Using the side-carry handles, lift the unopened end of the unit, pivoting on the endcap that is already opened and secured. As the SMU is raised into position, rest the weight of the unit on your thigh, allowing you to unlock the two latches holding the endcap against the main frame. If a third person is available to help, they should be positioned at the end of the SMU to help unlock the latches.



8. Once unlocked, slowly lower the endcap into position (do not allow endcap to drop).

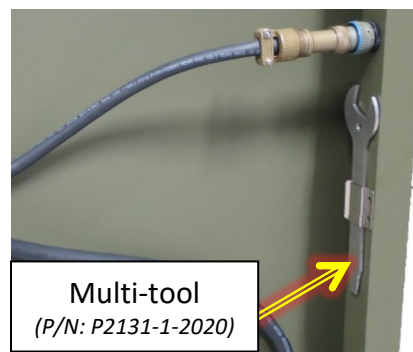
WARNING: A potential pinch point exists near the hinge area of the endcap. It is very important to keep hands positioned on the SIDES of the endcap.



9. Once the endcap is lowered into position, screw the two black endcap knobs down securely. Ensure the endcap knobs are fully seated by checking to see if the white washer in between the knob and the spring does not spin. Do not overtighten.



10. Remove the SAB from the chamber of the SMU. The SAB contains items necessary to complete the assembly of the unit. Refer to Section 3.2.1 – Chamber Door Operation for instructions on operating the chamber door. The multi-tool is stored in the rear endcap and will also be used (for S/N's AFS-0001 through AFS-0215, the multi-tool is in the SAB).



11. Remove left side panel of SMU with the multi-tool supplied in the rear endcap leg and perform visual inspection. On S/N's AFS-0001 through AFS-0215, the multi-tool is stored in the SAB. Ensure that:
 - a. HEPA filter cartridge is not damaged.
 - b. All wiring, hoses, and fittings are secure.
 - c. Insulation is not damaged.
 - d. There are no other visible issues or concerns.

CAUTION: Hold panel firmly in place when loosening the panel latches.

12. Remove right side panel of SMU (side with inlet air filter to the electrical enclosure) and perform visual inspection to ensure that:
 - a. There are no loose or disconnected wires.
 - b. There are no damaged or loose components.
 - c. The fuses are in place and not damaged.

CAUTION: Hold panel firmly in place when loosening the panel latches.

13. Remove top panel and front/back panels of the WRS to ensure that:
 - a. There are no loose or disconnected wires.
 - b. There are no damaged or loose components.

14. Clean and wipe down the unit as needed and reinstall all panels.

15. Place the WRS next to the SMU, orienting the unit such that the side of the WRS with the power switch and sight glass are on the right side of the SMU when facing the front of the SMU. Then, slide the WRS under the SMU.

The final positioning of the WRS should look like the picture below. The red, white, and blue hose connections should be on the side with the SMU's serial number plate as shown below. The sight glass and power switch for the WRS should be on the same side as the air inlet louvers for the SMU electrical box.



16. Remove the lower front panel of the SMU to access the connection for the condensate hose. Use the multi-tool provided in the SAB to loosen the front panel latches, and then gently remove the panel.



17. On the bottom left side of the SMU is an access hole for the condensate hose (red-tagged). Push the hose through this hole and unscrew the cap on the left side of the drain manifold. Ensure the O-ring on the manifold fitting is in place, and then connect the hose to the condensate outlet on the chamber drain manifold. Hand-tighten the nut and then tighten **45°** (max) using the multi-tool.

NOTE: If the fitting O-ring is missing, spare O-rings are provided in the SAB.



18. Replace the lower front panel.

19. On the WRS, unscrew the “Condensate from Sterilizer (IN)” bulkhead cap, and verify that the O-ring on the bulkhead fitting is in place. Attach the red-tagged condensate hose. The connection has a red bulkhead retainer to match the red tag on the hose. Hand-tighten the nut and then tighten 45° (max) using the multi-tool.

NOTE: If the fitting O-ring is missing, spare O-rings are provided in the SAB.



20. On the back of the SMU, unscrew the “Vacuum/Exhaust to WRS (OUT)” bulkhead cap, and verify that the O-ring on the bulkhead fitting is in place. Attach the white-tagged vacuum/exhaust hose. The connection has a white bulkhead retainer to match the white tag on the hose. Hand-tighten the nut and then tighten 45° (max) using the multi-tool.

NOTE: If the fitting O-ring is missing, spare O-rings are provided in the SAB.



21. On the WRS, unscrew the “Vacuum/Exhaust from Sterilizer (IN)” bulkhead cap, and verify that the bulkhead fitting O-ring is in place. Attach the white-tagged vacuum/exhaust hose. The connection has a white bulkhead retainer to match the white tag on the hose. Hand tighten the nut and then tighten **45°** (max) using the multi-tool.

NOTE: If the fitting O-ring is missing, spare O-rings are provided in the SAB.

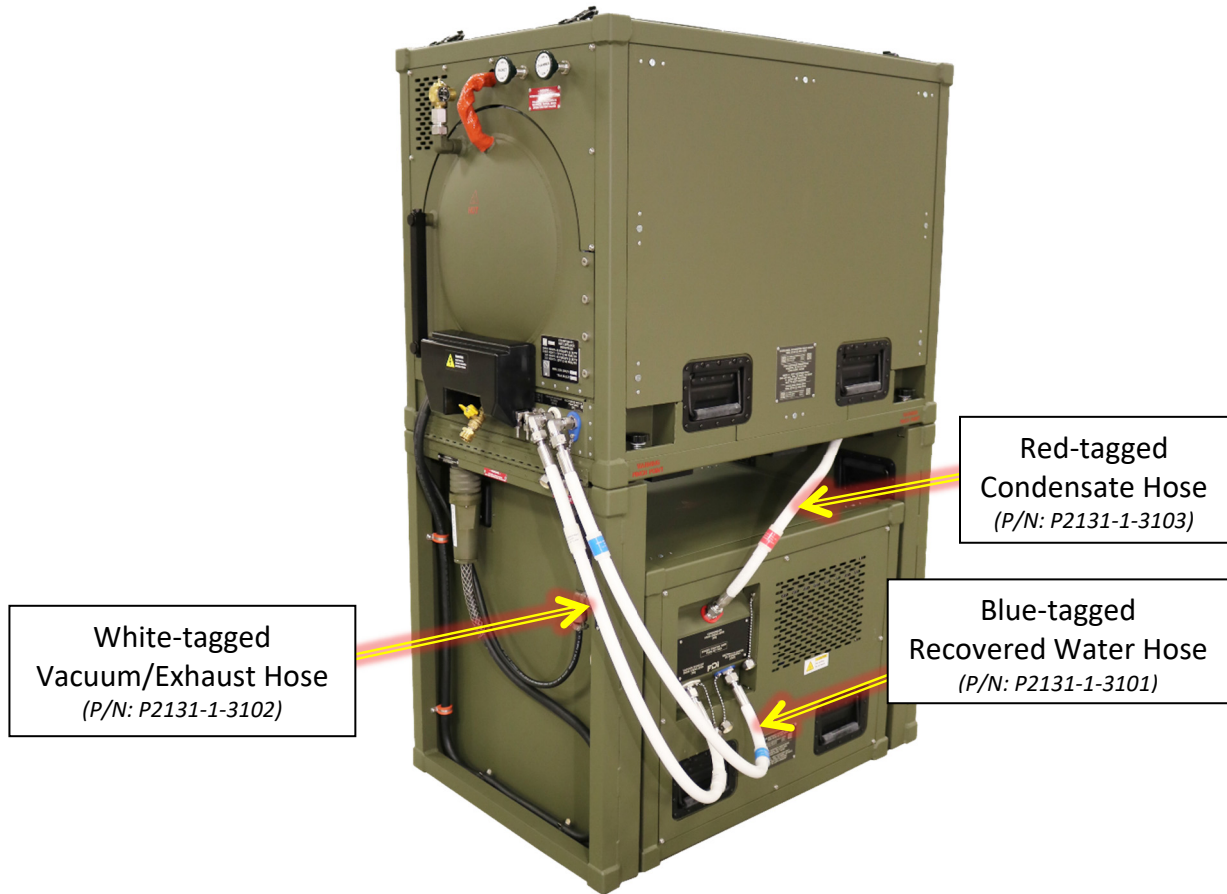


22. On the back of the SMU, unscrew the “Recovered Water from WRS (IN)” bulkhead cap, and verify that the bulkhead fitting O-ring is in place. Attach the blue-tagged recovered water hose. On the WRS, unscrew the “Recovered Water to Sterilizer (OUT)” bulkhead cap, and verify that the bulkhead fitting O-ring is in place. Attach the blue-tagged recovered water hose. These connections both have blue bulkhead retainers to match the blue tag on the hose. Hand tighten the nuts and then tighten **45°** (max) using the multi-tool.

NOTE: If a fitting O-ring is missing, spare O-rings are provided in the SAB.

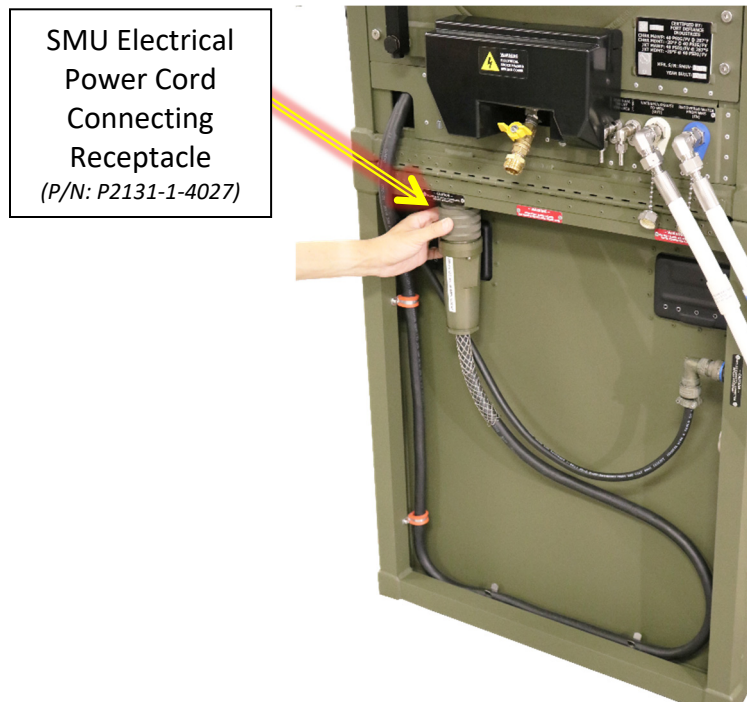


23. The final hose configuration is pictured below.

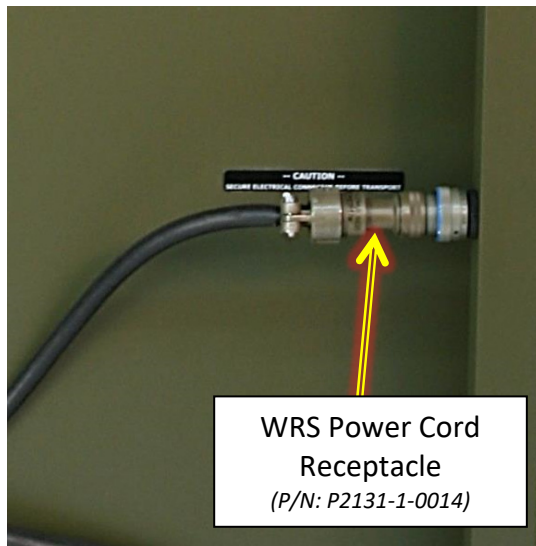


24. Unscrew the SMU power cord receptacle from its holder and set to the side.

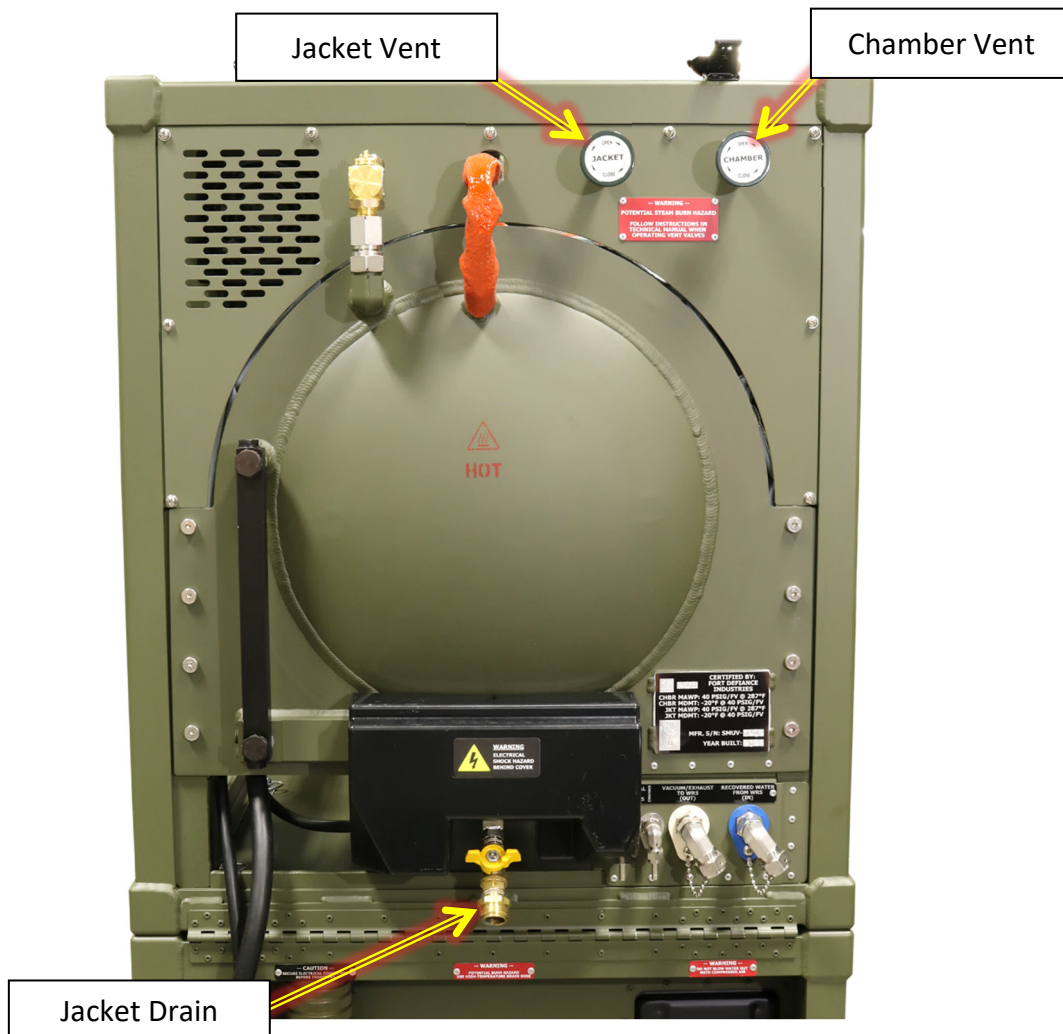
CAUTION: Do not connect this receptacle to a power source yet.



25. Remove the WRS Power Cord Receptacle (P/N: P2131-1-0014) from its holder and connect the receptacle into the WRS Main Power Plug (P/N: P2131-1-4010) on the WRS.



26. Ensure all three manual valves on the back of the SMU are closed firmly.

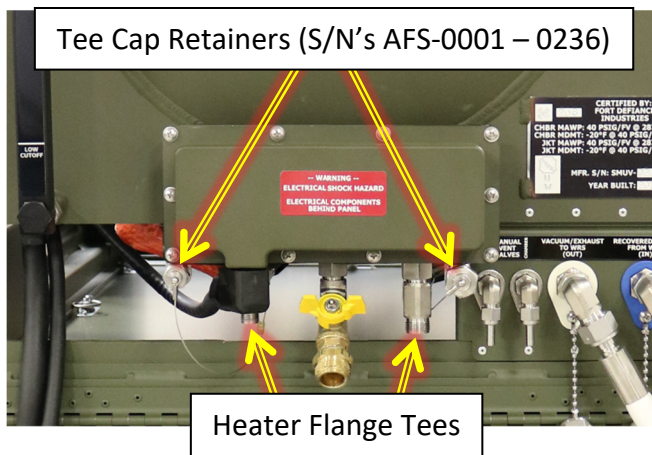


27. For S/N's AFS-0001 through AFS-0203, open the chamber door, and insert the chamber drain screen in the front of the chamber. The screen is in the large plastic bag found in the SAB. For S/N's after AFS-0203, verify the drain screen is already installed in the chamber. Do NOT operate the P2131 sterilizer without the chamber drain screen.

NOTE: Remove the screen by rotating and pulling the screen upwards. The screen is not designed to be tightened. For S/N's AFS-0001 through AFS-0203, the screen has an outward notch on the collar. For S/N's after AFS-0203, the drain screen has an O-ring that locks the screen into the coupling in the bottom of the chamber.



28. For S/N's after AFS-0236, the following step can be skipped. For S/N's AFS-0001 through AFS-0236, first remove Back Lower Panel and black Heater Assembly Cover. Reinstall the two Heater Flange Drain Caps at the rear of the unit by removing the caps from Tee Cap Retainers and tightening them to the Heater Flange Tees finger tight, then only one quarter-turn with wrench. Reinstall Back Lower Panel and Heater Assembly Cover.



29. Connect the high-temperature drain hose to the drain connection on the back of the SMU and ensure the jacket drain valve is closed. Ensure the opposite end is securely anchored to prevent hose whip in the unlikely event that pressurized steam or hot water is drained through this hose. Ensure layout of the hose is not a tripping hazard when accessing the sterilizer.

WARNING: Hot condensate and steam can rupture a standard garden hose. Only use the high temperature hose provided to drain the SMU or WRS.

30. Using the shims provided in the side zipper section of the SAB, elevate the rear of the SMU to ensure there is a slight decline from the back of the unit toward the front to allow the condensate in the chamber to drain properly. From a level starting point, this will be approximately 4 shims or 1" under the rear endcap. The target angle is 1.5°.



31. To test for proper angle, pour a cup of water in the back of the chamber, and ensure that it flows to the chamber drain.
32. Clean the chamber, and then install the trays found in the SAB.

CAUTION: Do not allow sand, chemicals, or other debris to flow down the chamber drain into the WRS. This could contaminate the water or damage components in the WRS.



33. Ensure that the power switches for the SMU and WRS are in the OFF position.

34. Connect the SMU power receptacle to a de-energized incoming power supply to ensure a surge-free installation, and then turn on the incoming power. The layout of the power cord should provide safe access to the sterilizer.

NOTE: User is responsible for compliance with applicable local and national electrical codes and regulations.

35. If a pressurized potable water source is available, connect a water supply to the INLET of the SWS. Before each use, flush SWS until water is clear (2 minutes). Before filling WRS, check water TDS (Total Dissolved Solids) and free chlorine level. Reference Section 3.4 for more details. See Section 2.5 – Water Supply Quality to ensure the correct quality of feedwater is used.

CAUTION: Water in SWS can foul and become discolored if not used regularly.



36. For S/N's AFS-0001 through AFS-0236, with the yellow valve handle as shown below, connect the clear Outlet Hose from the SWS to the Fill Connection on the bottom of the WRS. This is a cam-style connection. Ensure WRS drain valve is closed, then open the yellow valve on the end of the SWS outlet hose (pictured below) to allow water to flow into the tank. Once the HIGH mark is reached, close the yellow valve at the end of the SWS outlet.

For S/N's after AFS-0236, connect the Outlet Hose from the SWS to the Water Fill Connection on the WRS. Ensure the Tank Drain and Pump Drain valves are closed, then open the yellow valve on the end of the SWS outlet hose and the blue valve on the Water Fill Connection. Fill with water. Once the HIGH mark is reached, close the yellow valve at the end of the SWS outlet hose and the blue valve on the Water Fill Connection.



(S/N's AFS-0001 through 0236)



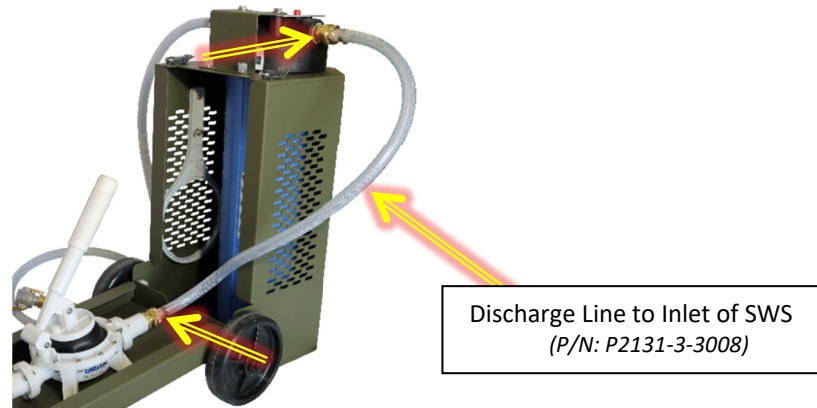
(S/N's after AFS-0236)

NOTE: If a pressurized water source is not available, the manual hand pump mounted on the SWS can be used to pump potable water from a bucket or Jerry can. Before each use, flush SWS until water is clear (2 minutes).

- Release the two Handle Latches and fold the handle down to expose the manual hand pump and hoses. Connect the Suction Line and drop strainer into a Jerry can or bucket.



- Hook hand pump Discharge Line to Inlet of SWS.



- Push/pull the white handle back and forth to pump water into the WRS. Once the HIGH mark is reached, close the yellow valve at the end of the SWS outlet hose and the blue valve on the Water Fill Connection.



37. Flip the power switch on the WRS to the ON position (UP position).



38. Close and tighten the chamber door. Flip the control power switch on the SMU to the ON position (UP position).



NOTE: When the SMU is turned ON with no water in the jacket, a “Low Water” alarm will occur and the WRS will turn ON. This alarm confirms that the liquid level switch is functioning correctly in the “Low Water” position. The alarm will prevent the heater elements from energizing, but will allow operation of the WRS to fill the jacket with water. (The “Low Water” alarm will be reset in a later step).

WARNING: If this “Low Water” alarm does not occur, turn the sterilizer OFF immediately to prevent damage to the heater elements. Contact a qualified maintenance technician to troubleshoot the liquid level switch and/or the liquid level switch plumbing.

LED Indicator Light Reference Guide:

Green = Successful cycle

Yellow = Jacket warming up

Red = Alarm

No light = Idling or in a cycle

39. Ensure the jacket vent valve on the back of the SMU is fully open and close the chamber vent valve. This will allow the jacket to vent the air while it is filled with water from the WRS. Minimizing air in the jacket improves sterilizer performance since air acts as an insulator during sterilization.
40. Press and hold the “Water to Sterilizer” button on the WRS and fill the SMU to the HIGH mark on the level sight glass. This should pump about 4.25 gallons of water into the jacket of the sterilizer. Add water to the WRS with the SWS as needed to fill the SMU to the HIGH mark.



CAUTION: Verify the SMU sight glass fills from the bottom. If not, contact a qualified maintenance technician to inspect the sight glass plumbing for debris.

CAUTION: Never add water to the jacket during a cycle. This will cause the jacket to cool, lose pressure, and alarm.

41. Firmly close the jacket vent valve on the back of the SMU.
42. Refill the WRS back to its HIGH mark and disconnect the SWS hose.

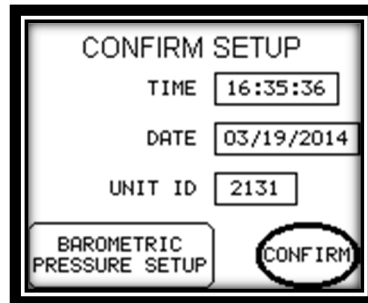
<p>NOTE: The correct water levels are HIGH/HIGH - when the water is at the HIGH mark in the jacket, the water level should be at or near the HIGH mark in the WRS.</p>

43. Reset the “02 – LOW WATER LEVEL” alarm. If the alarm clears, the liquid level switch is functioning correctly in the “Water OK” position.

CAUTION: If this “Low Water” alarm does not reset, contact a qualified maintenance technician to inspect the liquid level switch and liquid level switch plumbing.

44. On the "CONFIRM SETUP" screen, make any necessary updates to the TIME, DATE, or UNIT ID. To do so, touch the box to the right of the metric that needs to be updated. A new screen will appear for the user to make any desired updates. This screen will appear every time the Control Power is turned ON.

NOTE: The UNIT ID function allows for a unique identification to show in the top left-hand corner of the “Log” screen after each cycle for recording results. This can be especially helpful if there is more than one sterilizer in operation. The factory default for this UNIT ID is 2131. This can be changed as desired by the user.



45. Barometric Pressure Setup. Since the P2131 sterilizer is designed for altitudes ranging from sea level to 8,000 feet, the “BAROMETRIC SETUP” screen is used to set the gauge pressure in the PLC to zero.

NOTE: The sterilizer control system uses absolute pressure transmitters for cycle operation. By pressing ZERO, the controller knows the exact atmospheric pressure so that the chamber can be vented consistently to 0 psig (equal to atmospheric pressure). This allows the chamber door to be opened easily, and not be locked with a vacuum.

- From the “CONFIRM SETUP” screen, press the “BAROMETRIC PRESSURE SETUP” button.
- Open the chamber door completely so that the chamber and pressure transmitter are exposed to atmospheric pressure.
- Once the door is wide open, press the “ZERO” button on the “BAROMETRIC SETUP” screen.
- Press the “BACK” button to return to the “CONFIRM SETUP” screen.



- Press “CONFIRM” to proceed.

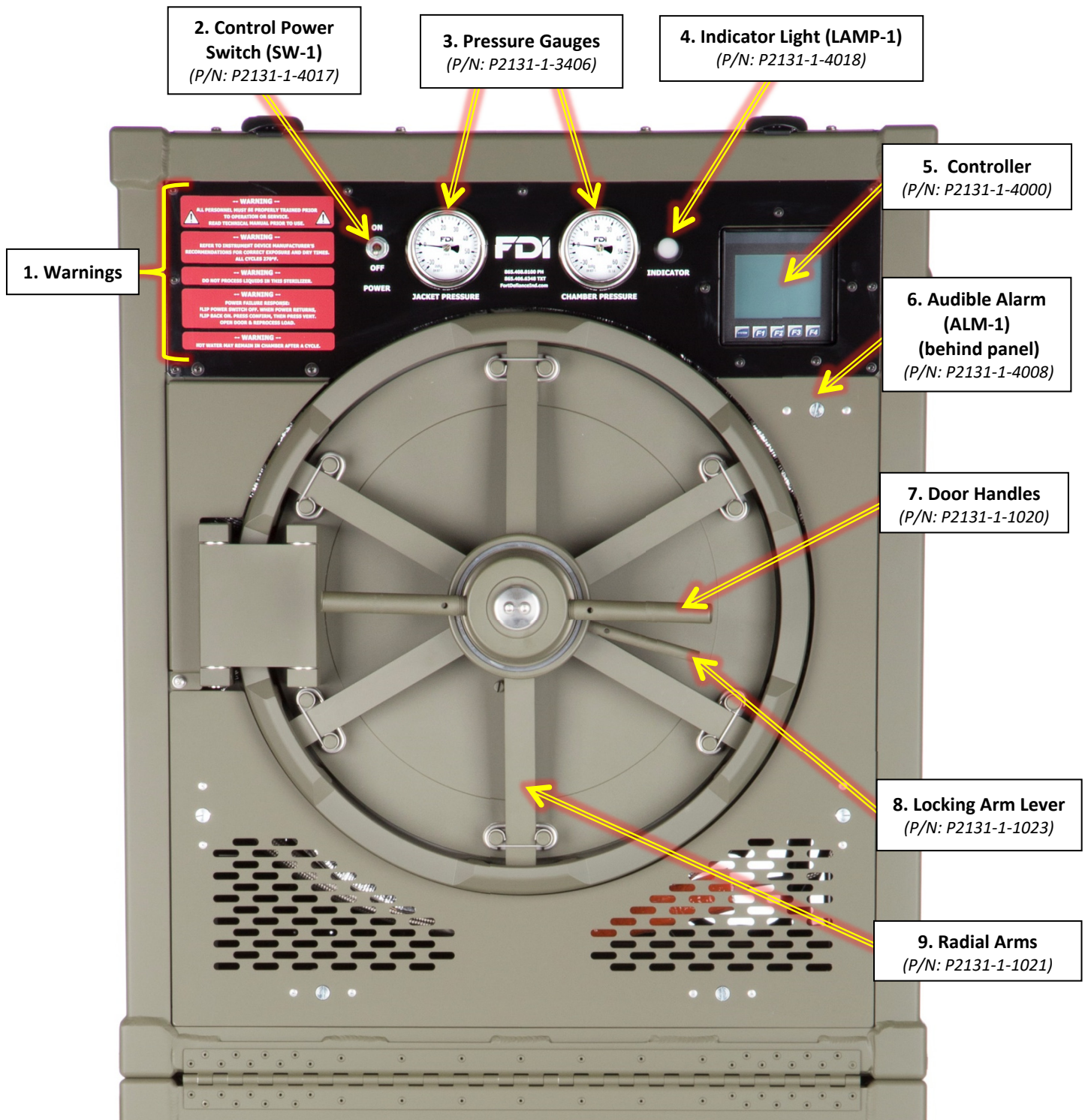
46. Navigate to the “STATUS” screen. With the door closed but not tightened, verify the door switch functions by raising and lowering the locking arm lever while observing “DOOR CLOSED” and “DOOR OPENED” on the screen. See Section 4.3.15 if there are any issues.
47. Perform the Pressure Safety Valve (PSV) Test. Reference Section 4.1 for instructions.
48. Run an IUSS (Immediate Use Steam Sterilization) cycle with an empty chamber to warm up the SMU. (Reference Section 3.3.3 for procedure.) After the cycle, open the door and inspect that no condensate has pooled around the chamber drain. If condensate pooling occurs, contact qualified maintenance technician to inspect the Steam Trap.
49. To ensure that the entire system of valves, fittings, and hoses are air-tight, run a VACUUM LEAK TEST. (Reference Section 3.3.4 for procedure.)
50. Run three successful BOWIE-DICK tests per the AAMI standards and the test pack manufacturer’s recommendations. This test will ensure that the air removal process during the pre-vac phase is working correctly. (Reference Section 3.3.4 for procedure.)
51. Perform Performance Qualification using PCDs per AAMI ST79 standards. Reference Section 2.6 for information on recommended sterility assurance products.
52. After all of these tests are successful, the P2131 sterilizer is ready for OPERATION. If any of these tests fail, the sterilizer cannot be placed into service. Call a qualified maintenance technician for repair. It is critical to reference Section 3.2 to become familiar with all Controls & Indicators before following the Operating Procedure in Section 3.3.

WARNING: When not in use, the SMU, the WRS, and the SWS should be drained completely to prevent potential growth of biological matter. The SWS can be drained by removing the hoses from the inlet/outlet and turning the unit upside down to allow all the water to drain out. Reference the checklist for Transport and/or Storage in Section 3.7.

WARNING: If freezing temperatures are possible around the sterilizer, all water from the SMU, WRS, and SWS must be drained to prevent possible freezing and damage to the pressure vessel, pump, SWS housing, or other components. Reference Section 3.7 for information on draining water.

3.2 Controls and Indicators

Sterilizer Main Unit (SMU)



Front View of SMU

Function(s) of Control or Indicator (Front View of SMU)

ITEM	CONTROL/INDICATOR	FUNCTION
1.	Warnings	Critical warnings for the safe operation and maintenance of the P2131. Be sure to reference all warnings listed in Section 1.1.
2.	Control Power Switch	A two-position toggle switch that energizes the control system and heater elements. Up position is ON, and down is OFF.
3.	Pressure Gauges	Indicates gauge pressure (psig) in jacket and chamber.
4.	Indicator Light	Green = Successful cycle Yellow = Jacket warming up Red = Alarm No light = Idling or in a cycle.
5.	Controller	Touch-screen controller for operating the P2131 sterilizer. For details on the menu, screens, and all functions, reference Section 3.3 - Operating Procedure.
6.	Audible Alarm	Buzzer/alarm to audibly notify the operator of conditions. Single tone = successful cycle Three tones in rapid sequence = alarm notification Sustained Tone = Low water & Liquid Level Switch malfunction or damaged HTS-1 RTD
7.	Door Handles	Turning these handles tightens and seals the door into place. These handles may become warm during operation.
8.	Locking Arm Lever	Pivots the radial arms to lock the door into place as well as activating the door switch.
9.	Radial Arms	Engages with the door frame to lock the door closed. When retracted, the door can be opened.

3.2.1 CHAMBER DOOR OPERATION:

WARNING: Steam and/or hot water can remain in the chamber after a cycle.

NOTE: If a vacuum exists in the chamber, vent by pressing VENT on the PLC or open the manual chamber vent valve on the back of unit.

The chamber door is operated by a combination of the Door Handles and the Locking Arm Lever

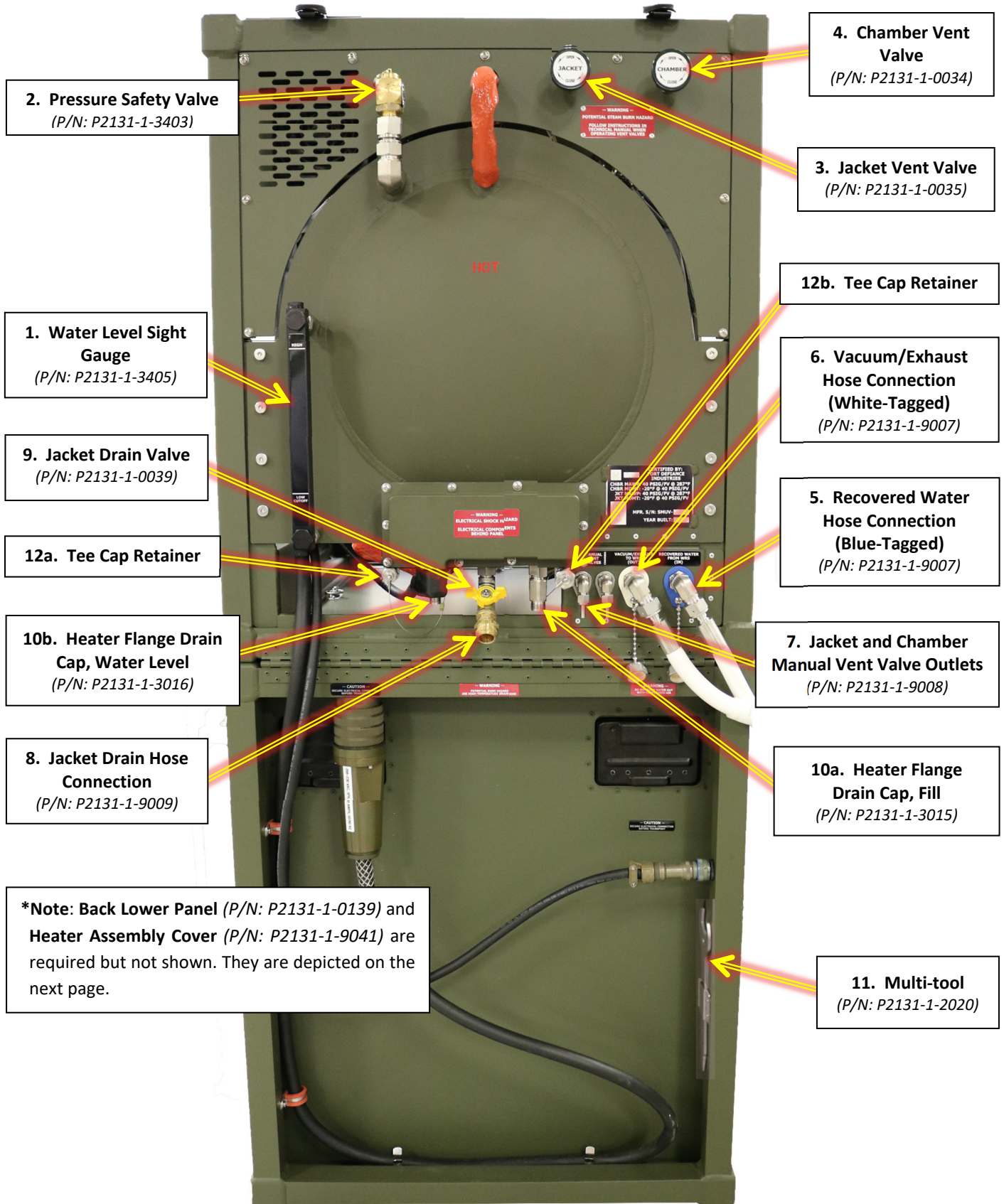
To open the door:

1. Rotate the Door Handles counter-clockwise until the handles stop.
2. Pull upwards on the Locking Arm Lever until the Radial Arms are fully retracted.
3. The door can now be swung open by pulling on the Door Handles or Locking Arm Lever.

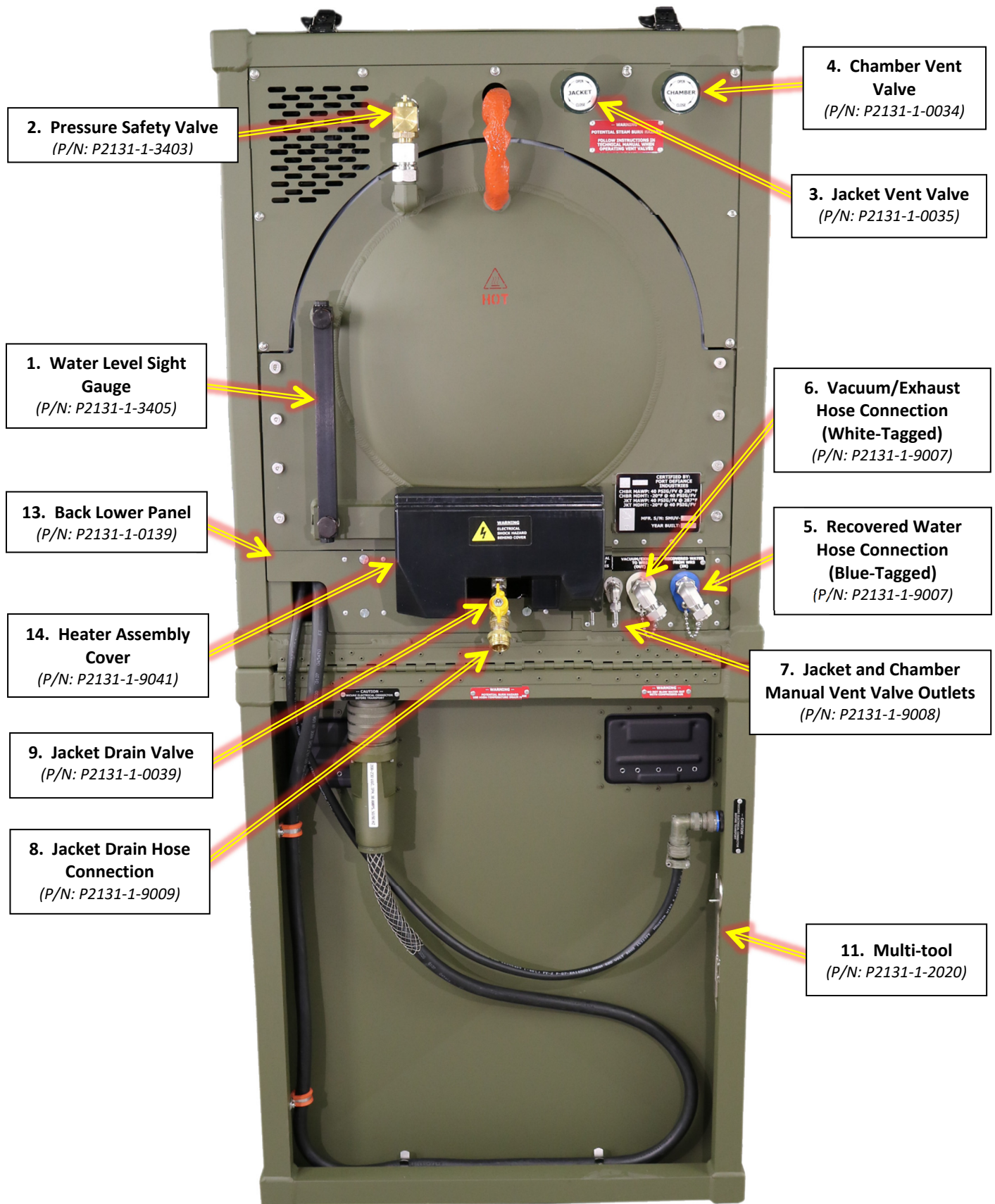
To close the door:

1. Ensure the Locking Arm Lever is in the up position so that the Radial Arms are fully retracted.
2. Slowly swing the door closed and then push the Locking Arm Lever down to extend the Radial Arms.
3. Rotate the Door Handles clockwise until tight.

Rear View of SMU for S/N'S AFS-0001 though AFS-0236



Rear View of SMU for S/N'S after AFS-0236



Function(s) of Control or Indicator (Rear View of SMU)

ITEM	CONTROL/INDICATOR	FUNCTION
1.	Water Level Sight Gauge	Indicates water level inside jacket. Fill to HIGH mark. A low water level switch (separate from sight gauge and not shown in picture) will create an alarm, abort the cycle, and de-energize the heaters.
2.	Pressure Safety Valve (PSV)	Relieves overpressure @ 40 psig to prevent potential rupture of jacket/chamber
3.	Jacket Vent Valve	Manual valve that opens the jacket to atmosphere. This valve <u>must be closed</u> during normal operation. Best practice includes NOT opening this valve after shutdown to vent steam, but allow SMU to cool and steam to condense (this will pull a vacuum in jacket, which is OK).
4.	Chamber Vent Valve	Manual valve that opens the chamber to atmosphere. This valve <u>must be closed</u> during normal operation. This valve is used to relieve pressure or vacuum (e.g., if vacuum develops in chamber from accidentally leaving door closed during cool down).
5.	Recovered Water Hose Connection (Blue-Tagged)	This hose supplies water to the jacket from the WRS.
6.	Vacuum/Exhaust Hose Connection (White-Tagged)	This hose exhausts steam/air and allows the WRS to create the vacuum necessary for sterilizer operation.
7.	Jacket and Chamber Manual Vent Valve Outlets	Outlet points for the Jacket and Chamber vent valves. WARNING: A small amount of hot condensate will collect above these valves during operation. Slowly crack the valve to allow any hot condensate to empty out and keep hands away from this outlet point.
8.	Jacket Drain Hose Connection	Hose connection draining hot water from jacket. ONLY use the high temp hose provided to drain jacket. Ensure end of hose is secured to prevent hose whip in the unlikely event of pressurized steam exhausting from this hose. WARNING: A standard garden hose could rupture, resulting in potential burns.
9.	Jacket Drain Valve	Manual valve that opens the jacket to atmosphere and allows the jacket to drain. This valve <u>must be closed</u> during normal operation. Do not open this valve with pressure on jacket.
10.	Heater Flange Drain Caps	S/N's AFS-0001 through AFS-0236: Used to drain heater flange tees for transport and/or storage.
11.	Multi-tool	Used during the setup of the sterilizer to tighten hoses and remove panels.
12.	Tee Cap Retainer	S/N's AFS-0001 through AFS-0236: Used to store Heater Flange Drain Caps during Transport and/or Storage of the Sterilizer.
13.	Back Lower Panel	This panel prevents the user from accessing underneath the Chamber.
14.	Heater Assembly Cover	This cover protects the user from any potential electrical shock hazard.

**1. Inlet Air Filter
(behind panel)**
(P/N: P2131-1-5001)



**2. Endcap Knob
(P/N: P2131-1-0020)**

**3. Carry Handle
(P/N: P2131-1-5011)**

Right Side of SMU

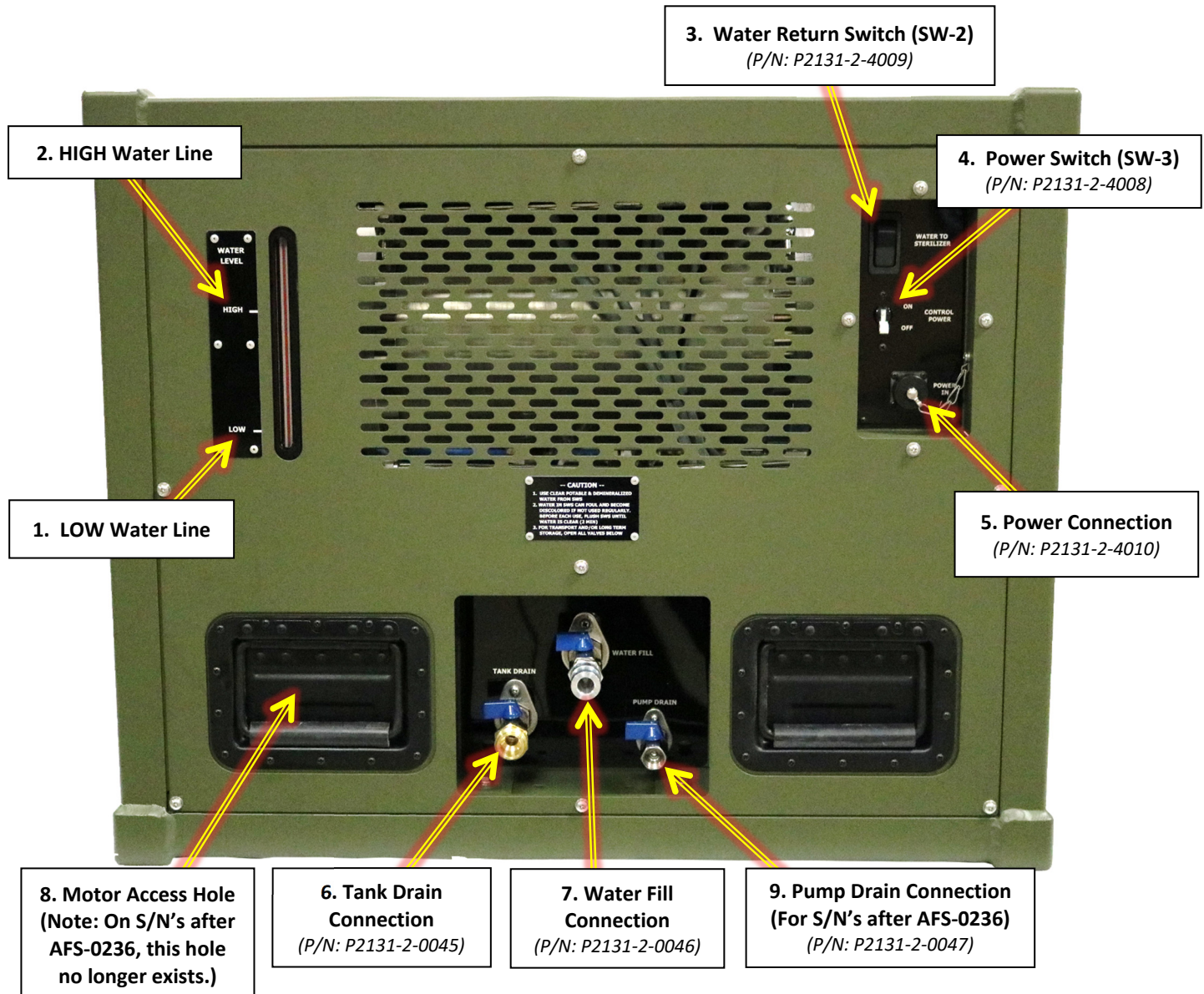
Function(s) of Control or Indicator (Right Side of SMU)

ITEM	CONTROL/INDICATOR	FUNCTION
1.	Inlet Air Filter (behind panel)	Filters air for cooling electrical components. Filter is washable and should be inspected and cleaned. Reference Section 4, Post-Maintenance Checklist.
2.	Endcap Knob	Located on each corner of the SMU, these are used to secure endcap in down position during setup. When breaking down the sterilizer for storage or transport, the endcap knobs should be turned counter-clockwise. When the knobs disengage from the endcap, a spring will pop them upwards, indicating they are free.
3.	Carry Handle	Recessed spring-loaded handle used for transporting the SMU.

Water Recovery System (WRS)

The WRS reclaims steam and condensate from the SMU for re-use. A circulation pump and heat exchanger allow for hot steam to be cooled and condensed into water. A water eductor creates a vacuum during the preconditioning phases to remove air and provides a deep vacuum to assist in drying a load during the dry phase. The WRS also provides an easy, push-button method to refill the SMU jacket.

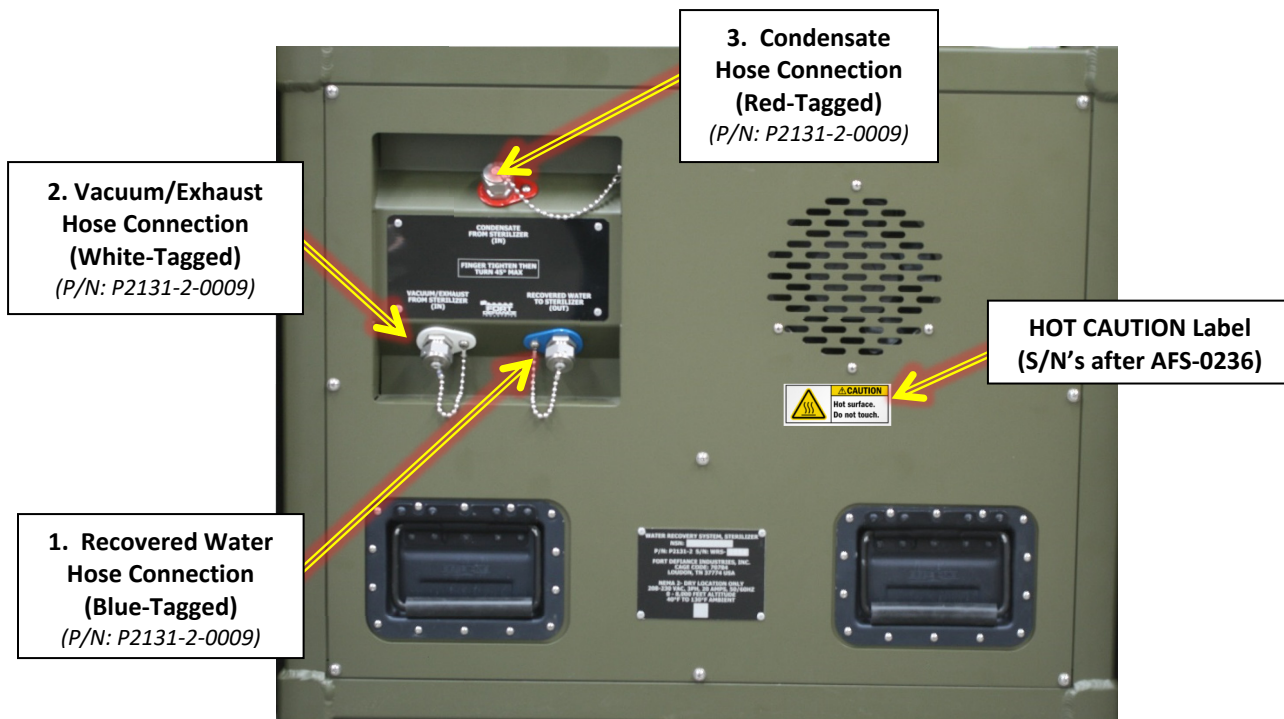
NOTE: The Power Switch on the WRS should always be in the ON position during operation.



Right Side of WRS

Function(s) of Control or Indicator (Right Side of WRS)

ITEM	CONTROL/INDICATOR	FUNCTION
1.	LOW Water Line	Water level in the tank is indicated by the position of a floating ball inside the Sight Gauge tubing. On S/N's after AFS-0236, a water line in the Sight Gauge tubing indicates the water level. During operation, the water level should be at or near the HIGH water line (when the jacket is at the HIGH mark). If the water level becomes too low, the Low Level Switch (located underneath the tank near the motor) will activate and prevent the pump from running dry. If the pump starts and stops, or will not operate, water likely needs to be added to the WRS.
2.	HIGH Water Line	Water level in the tank is indicated by the position of a floating ball inside the Level Gauge tubing. On S/N's after AFS-0236, a water line in the Sight Gauge tubing indicates the water level. During operation, the water level should be maintained at or near the HIGH water line. Overfilling and running the WRS with water above the HIGH mark (when the jacket is at the HIGH mark) may result in water "burping" out of the relief vent or breather on top of the WRS water tank.
3.	Water Return Switch (SW-2)	A push-button that turns ON the pump to flow water into the sterilizer when pressed. Releasing the switch will stop the flow of water.
4.	Power Switch (SW-3)	A two-position switch that turns electricity ON and OFF to the WRS. This switch also has a 20-amp circuit breaker built into the switch.
5.	Power Connection	Where the power cord from the SMU is plugged into the WRS to provide power to the WRS.
6.	(Tank) Drain Connection	Allows water to drain from the WRS. When the WRS needs to be drained, the high-temperature drain hose on the SMU can be used.
7.	(Water) Fill Connection	A male cam-and-groove fitting where the clear outlet hose from the SWS is connected.
8.	Motor Access Hole	An access hole to insert screwdriver to rotate motor (Note: For maintenance technician only. This hole no longer exists on S/N's after AFS-0236).
9.	Pump Drain Connection	Allows water to drain from Pump and Pump plumbing. (Note: For S/N's AFS-0001 – 0236, there is a petcock valve mounted directly on the pump).



Left Side of WRS

Function(s) of Control or Indicator (Left Side of WRS)

ITEM	CONTROL/INDICATOR	FUNCTION
1.	Recovered Water Hose Connection (Blue-Tagged)	This hose carries water from the WRS into the jacket in the SMU when the water return switch is depressed.
2.	Vacuum/Exhaust Hose Connection (White-Tagged)	This hose exhausts steam/air from the SMU chamber and connects to a water eductor inside the WRS, which generates the vacuum needed for the pre-vac and post-vac stages of sterilization.
3.	Condensate Hose Connection (Red-Tagged)	This hose carries hot condensate from the SMU chamber to the WRS. A steam trap inside the WRS controls the flow of condensate.

Sterilizer Water Softener (SWS)

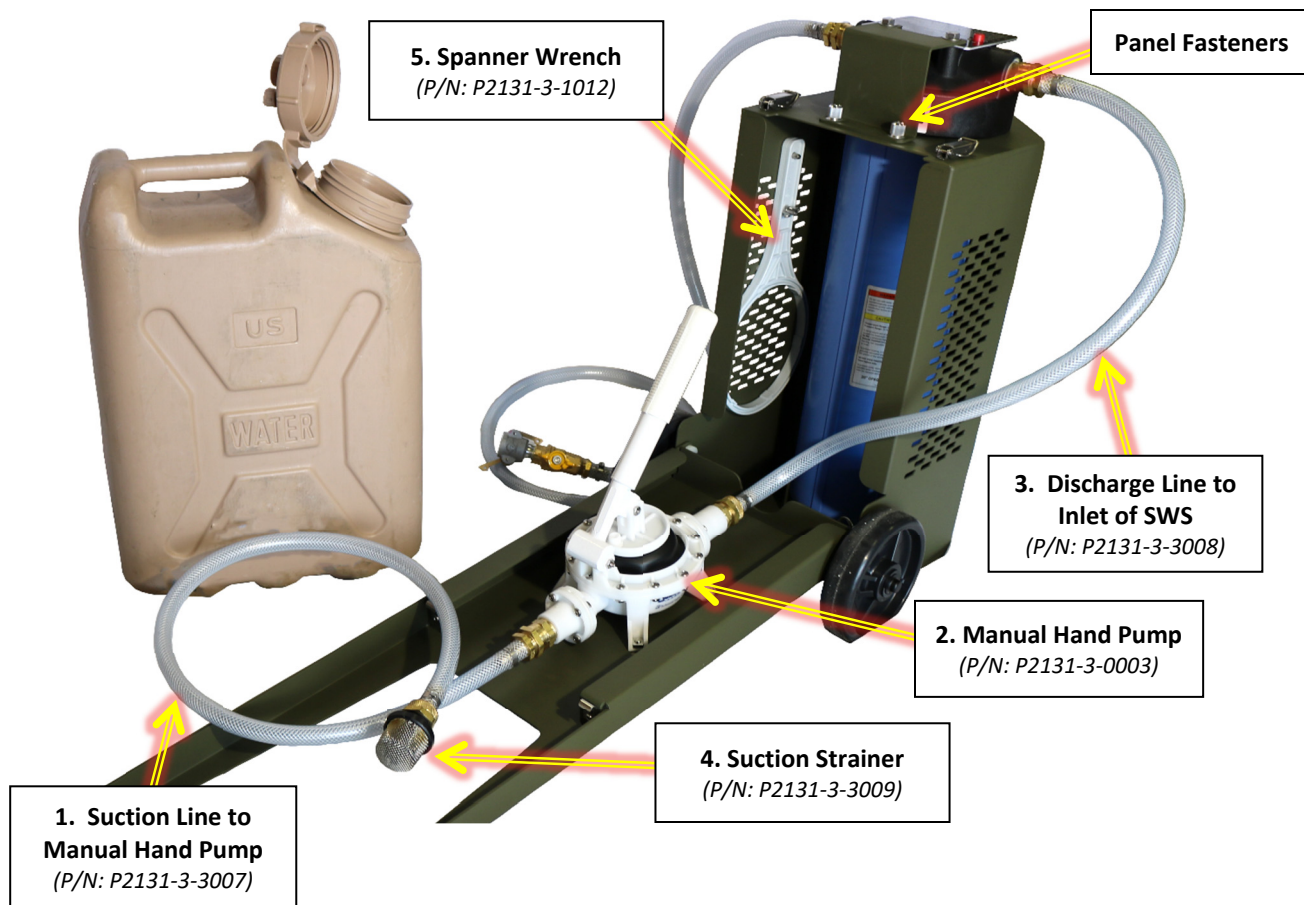
The SWS is critical to the long-term reliability and performance of the P2131 sterilizer. The purpose of the SWS is to remove ions (e.g., calcium, magnesium, and chlorides) from the water to prevent scale buildup on the heating elements, jacket walls, and other components.



Front View of SWS

Function(s) of Control or Indicator (Front View of SWS)

ITEM	CONTROL/INDICATOR	FUNCTION
1.	Inlet Hose Connection	Connect pressurized potable water supply hose to this connection. If not available, connect the outlet hose from the manual hand pump.
2.	Top Cap	Remove this cap to replace the deionized water cartridge. Reference cartridge replacement procedure in Section 4.3.4.
3.	Outlet Hose Connection	Discharge of deionized water to WRS.
4.	Outlet Hose (to WRS)	This hose is connected to the SWS outlet as well as to the WRS fill connection. The cam-and-groove fitting with ball valve is specifically designed to work with the WRS inlet.



Rear View of SWS

Function(s) of Control or Indicator (Rear View of SWS)

ITEM	CONTROL/INDICATOR	FUNCTION
1.	Suction Line to Manual Hand Pump	Used when manual hand pump is in service. Water flows from bucket or Jerry can through hand pump and into SWS.
2.	Manual Hand Pump	If a pressurized potable water supply is not available, pump potable water from bucket or Jerry can by rotating handle clockwise. Flow rate up to 8 gpm. Turn handle inwards for transport to prevent breakage.
3.	Discharge Line to Inlet of SWS	Carries water from hand pump to SWS inlet connection.
4.	Suction Strainer	Used when hand pump is in service. Strains out any potential debris from Jerry can or bucket from water before entering SWS.
5.	Spanner Wrench	Used to remove Top Cap from blue housing and replace the DI Cartridge.

3.3 Operating Procedure

Overview of Touch-Screen Operator Control Panel

The P2131 sterilizer is controlled with an advanced programmable logic controller (PLC) with a touch-screen display that performs pre-programmed sterilization cycles and performance tests.

NOTE: The following instructions assume that the P2131 sterilizer has been set up, checked out, and potable water is already in the SMU and WRS. Reference Section 3.1.

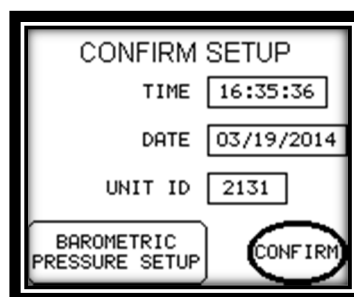
NOTE: The “System” and “F1” through “F3” buttons are disabled. The “F4” button is only used as part of maintenance of the PLC.

3.3.1 TURNING THE STERILIZER ON:

1. Flip up the Control Power Switch on the front panel to turn the sterilizer ON.
2. On the “CONFIRM SETUP” screen, make any necessary updates to the TIME, DATE, or UNIT ID. To do so, touch the box to the right of the metric that needs to be updated. A new screen will appear where you can make necessary updates.

NOTE: This screen will appear every time the Control Power is turned ON.

NOTE: The UNIT ID function allows for a unique identification to show in the top left-hand corner of the “Log” screen after each cycle for recording results. This can be especially helpful if there is more than one sterilizer in operation. The factory default for this UNIT ID is 2131. This can be changed as desired by the user.



3.3.2 ZEROING GAUGE PRESSURE (BAROMETRIC PRESSURE SETUP):

Since the P2131 sterilizer is designed for altitudes ranging from sea level to 8,000 feet, the “BAROMETRIC SETUP” screen is used to set the gauge pressure in the PLC to zero.

NOTE: The sterilizer control system uses absolute pressure transmitters for cycle operation. By pressing ZERO, the controller knows the exact atmospheric pressure so that the chamber can be vented consistently to 0 psig (equal to atmospheric pressure). This allows the chamber door to be opened easily, and not be locked with a vacuum.

1. From the “CONFIRM SETUP” screen, press the “BAROMETRIC PRESSURE SETUP” button.
2. Open the chamber door completely so that the chamber and pressure transmitters are exposed to atmospheric pressure.
3. Once the door is wide open, press the “ZERO” button on the “BAROMETRIC SETUP” screen.
4. Press the “BACK” button to return to the “CONFIRM SETUP” screen.



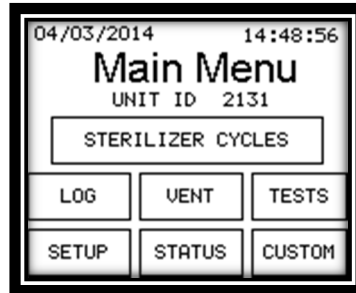
5. Press “CONFIRM” to proceed.

3.3.3 RUNNING A NORMAL STERILIZATION CYCLE:

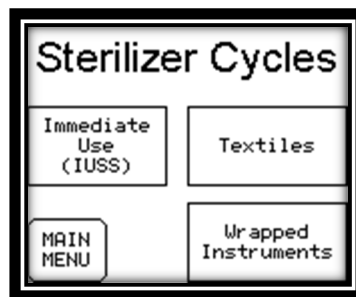
1. Assemble the items to be sterilized with the appropriate process challenge devices (PCDs), biological indicators, chemical integrators, etc. Reference Section 2.6 for information on sterility assurance products.

NOTE: The FDA-cleared PCD for the 4-minute and the 10-minute cycles can be purchased from FDI at (865) 408-0100 or via email at sales@fortdefianceind.com. Please see Appendix A.3 for more information.

2. Open the door. Insert items to be sterilized. Close and tighten the door. On the “Main Menu” screen, choose “STERILIZER CYCLES”.

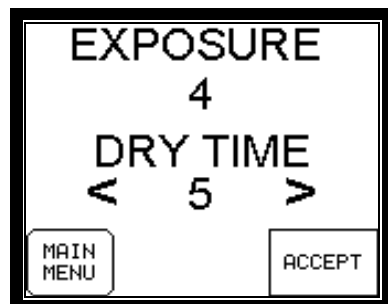


3. On the “STERILIZER CYCLES” screen, choose the type of sterilization cycle that you need to run.

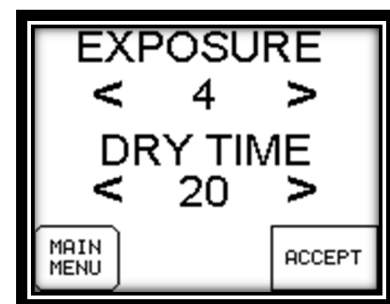


4. For the TEXTILES or WRAPPED INSTRUMENTS cycles, use the arrow buttons to select the desired dry time. For the WRAPPED INSTRUMENTS cycle, select the 4-minute or 10-minute exposure. Press the “ACCEPT” button.

CAUTION: For a 10-minutes sterilization cycle, the VERIFY™ 10-minute PCD must be used. Reference Section 2.6 for information on sterility assurance products.



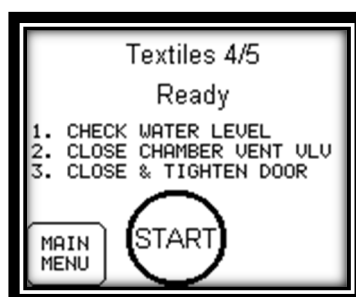
Textiles Cycle Screen



Wrapped Instruments Cycle Screen

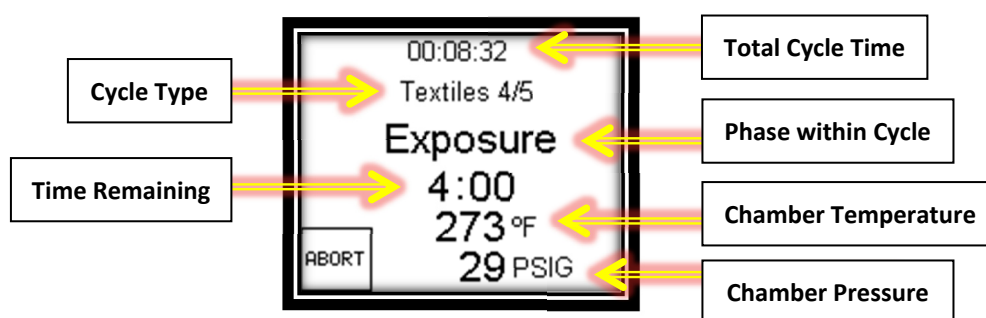
5. Verify that the jacket water level is sufficient, the chamber vent valve is closed, and the chamber door is closed and tightened. Then press “START” to initiate the cycle.

NOTE: When water is added to the jacket, there will be a slight cooldown, and therefore a reduction in pressure. The pressure in the jacket will need a few minutes to recover when water is added.



If the jacket is not at setpoint pressure (see NOTE above), the “START” screen will display “WARMING UP” instead of “Ready”. If you choose “START” before the jacket is ready, the “START” button will disappear and the display will show “Cycle Pending.” Once the jacket is up to setpoint pressure, the cycle will begin automatically.

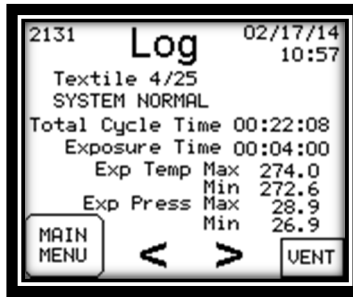
During the cycle, the run screen will display the total cycle time, type of cycle, phase within the cycle, the time remaining (for exposure, drying, or vacuum testing only), the chamber temperature, and the chamber pressure. A cycle can be aborted at any time by choosing the “ABORT” button. This will stop the cycle and vent the chamber.



6. At the end of the cycle, the buzzer will sound and the chamber will vent. Once the chamber is completely vented, the door can be opened.

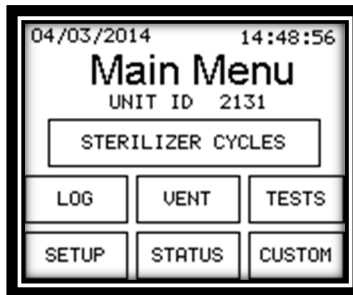
NOTE: Unlocking the door (which actuates the door switch) before the chamber reaches 0 psig will stop the venting and may create a situation in which the door may not open due to vacuum in the chamber. If this happens, lock the door and press “VENT” from the “Log” screen.

The “Log” screen will be displayed at the end of the cycle showing the results of the cycle. A total of 40 previous “Log” entries can be viewed using the LEFT and RIGHT arrows. The “Log” screen can also be accessed from the “Main Menu.”

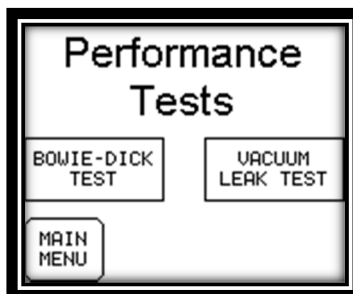


3.3.4 RUNNING A PERFORMANCE TEST:

1. On the “Main Menu” screen, choose “TESTS”.



2. On the “Performance Tests” screen, choose either “BOWIE-DICK TEST” or “VACUUM LEAK TEST.”



For a BOWIE-DICK TEST:

Place a U.S. Food and Drug Administration (FDA)-approved BOWIE-DICK test pack on the bottom rack near the drain in the chamber. Follow all test pack manufacturer’s recommended procedures. For example, a warmup cycle (e.g., IUSS 4/0) should always be run prior to the BOWIE-DICK test.

WARNING: A BOWIE-DICK test should be performed each day to ensure air removal is functioning properly during pre-vac. A BOWIE-DICK test should also be performed any time the sterilizer is set up at a new location or after maintenance work.

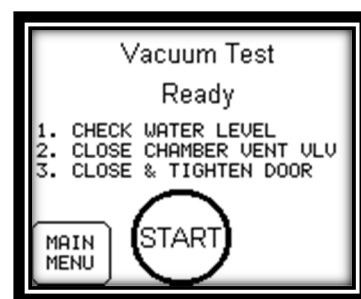
For a VACUUM LEAK TEST:

The sterilizer should be warmed up prior to running the VACUUM LEAK TEST by running any cycle (e.g., Textile 4/5) before the test.

The VACUUM LEAK TEST consists of two phases. The first phase is a settling phase (5 minutes) and the second phase is the test phase (15 minutes). The P2131 sterilizer will conduct both phases automatically, and a countdown timer will indicate the time remaining for each phase. At the end of a successful test, the “Log” screen will appear. An “ALARM” screen will appear if unsuccessful.

WARNING: A VACUUM LEAK TEST should be performed when the sterilizer is set up at a new location or after any major service or maintenance. In a hot environment the test may take longer because the WRS water may be hot, which affects the eductor’s ability to pull a deep vacuum. Perform the test when the WRS water has cooled down.

3. For either test, the “START” screen will be displayed.
4. Before starting the test, verify there is enough water in the jacket. If the water level is low, add water from the WRS. If you need to add water to the WRS, do so with the SWS.
5. Verify that the two vent valves on the back of the unit are closed.
6. Verify that the door is closed and tightened, then choose “START” to initiate the sterilization cycle.



If the jacket is not up to setpoint pressure, the “START” screen will display “Warming Up” instead of “Ready.” If you choose “START” before the jacket is ready, the “START” button will disappear and the display will show “Cycle Pending.” Once the jacket is up to setpoint pressure, the test will begin automatically.

During the cycle, the “RUNNING” screen will display the total cycle time, type of test, where it is in the cycle, the time remaining (during exposure or vacuum testing only), the chamber temperature, and the chamber pressure. A test can be aborted at any time by choosing the “ABORT” button. This will stop the test and vent the chamber.



7. At the end of the test, the buzzer will sound and the chamber will vent. Once the chamber is completely vented, the door can be opened.

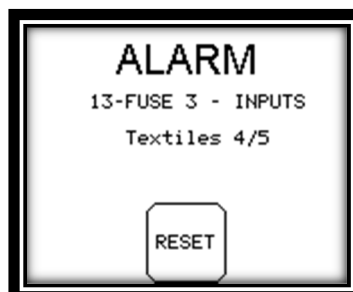
NOTE: Unlocking the door (which actuates the door switch) before the chamber reaches 0 psig will stop the venting and may create a situation in which the door may not open due to vacuum in the chamber. If this happens, lock the door and press “VENT” from the “Log” screen.

The “Log” screen will be displayed at the end of the test displaying the results of the test. Previous “Log” entries can be viewed using the LEFT and RIGHT arrows.

NOTE: If the VACUUM LEAK TEST fails, contact a qualified maintenance technician and follow the troubleshooting guide in Section 4.3.14.

3.3.5 ALARMS:

If an alarm goes off, the red ALERT light on the front panel will illuminate and the buzzer will beep three times. In addition, the sterilizer will vent and stop the cycle in a safe mode. It will display an “ALARM” screen that will show the alarm code and a description of the alarm. Reference Section 3.6 for an Alarm Code Troubleshooting Guide.



Choosing to “RESET” will either (1) switch the display to the “Log” screen or (2) repeat the same alarm if the condition is still present. The controller will not allow the sterilizer to continue until the alarm has been reset. For example, if the alarm was “02-Low Water Level,” water will need to be added to the jacket before the alarm will reset.

The controller will then display the “Log” screen with the details of the alarm for recordkeeping.

3.3.6 MAINTENANCE REMINDER:

Per FDA regulations, every 100 cycles or 14 calendar days, the water in the entire system must be drained and refilled. After every 100 cycles, a “Maintenance Reminder” screen is shown to remind the operator that the water in the SMU jacket, the WRS, and the SWS must be drained and replenished with fresh potable water. If needed, flush the SWS until clear (2-minute flush).

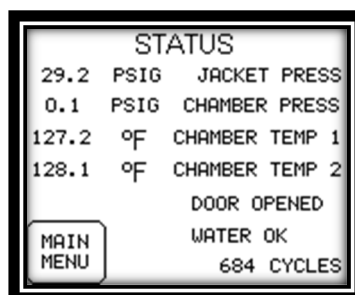
This reminder also serves to help encourage maintenance technicians to check and follow the recommended maintenance schedule (Reference Section 4).



3.3.7 STATUS:

The “STATUS” screen can be accessed (except when a cycle is running) in order to look at data such as jacket pressure, chamber pressure, chamber condensate temperature (both RTDs), whether the door switch is showing open or closed, if the water level is OK or low, and how many total cycles the unit has run.

This screen can be accessed by selecting the “STATUS” button from the “Main Menu” screen.

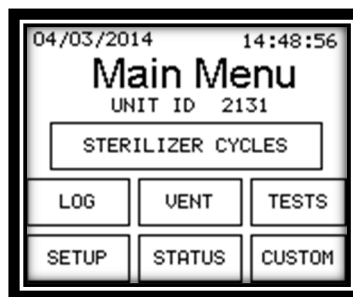


3.3.8 PROGRAMMABLE CYCLES:

WARNING: Only the standard AAMI cycles listed in Section 2.3 have been cleared by the FDA. Programmable cycles have not been validated. The FDA highly recommends that programmable cycles be used for research purposes. The user accepts all risks associated with sterilizing any load using a programmable cycle.

Programmable cycles allow the user to run cycles with exposure times that can range from 15 minutes to 40 minutes in increments of 5 minutes. Dry times can range from 0 to 60 minutes, also in 5-minute increments.

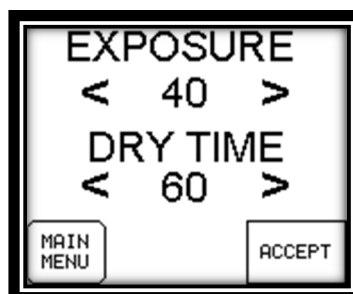
1. To run a programmable cycle, press “CUSTOM” from the “Main Menu”.



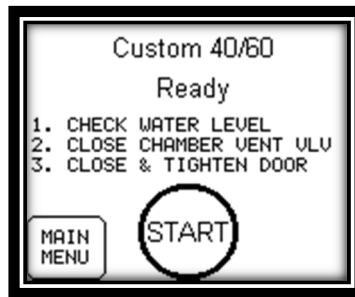
2. After carefully reading the **WARNING**, press “Accept” to continue.



3. Press the arrow keys to select the desired exposure and dry times, and then press “ACCEPT”.



4. After checking the water level, ensuring the chamber vent valve is closed, and tightening the door, press “START” to begin the cycle.



5. At the end of the cycle, the buzzer will sound and the chamber will vent. Once the chamber is completely vented, the door can be opened.

NOTE: Unlocking the door (which actuates the door switch) before the chamber reaches 0 psig will stop the venting and may create a situation in which the door may not open due to vacuum in the chamber. If this happens, lock the door and press “VENT” from the “Log” screen.

The “Log” screen will be displayed at the end of the cycle showing the results of the cycle. A total of 40 previous “Log” entries can be viewed using the LEFT and RIGHT arrows. The “Log” screen can also be accessed from the “Main Menu.”

Section 3.4 Operational Checklists



Four Critical Steps for Reliability

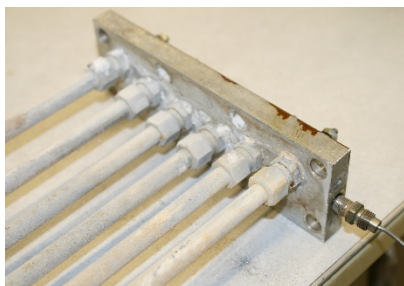


1. Connect clean potable water to the SWS. (Reference Section 2.5 – Water Supply Quality)
2. Use the SWS every time water is added to the WRS. Before each use, flush SWS until water is clear (2 minutes). Use chlorine test strips to verify water quality (Reference Section 3.4.3 Testing Free Chlorine). Water can foul and become discolored if not used regularly.
3. Test the TDS (Total Dissolved Solids) of the water and replace the deionized water cartridge as needed. (Reference Section 3.4.1 Testing Total Dissolved Solids and Section 4.3.4 SWS Cartridge Replacement)
4. Follow every step of Section 3.7 - Checklist for Transport and/or Storage to prevent storage-related issues upon startup.

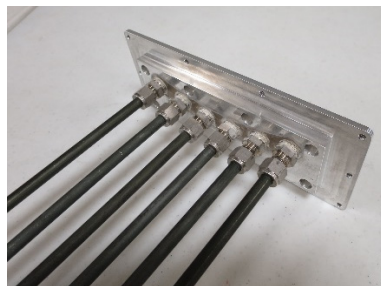
Why the SWS is Important:

Preventing scale buildup (buildup of mineral deposits) is critical for ensuring that the P2131 sterilizer continues to operate reliably for many years. Preventing scale buildup will keep heat-up times short. In addition, scale buildup can cause small pieces of scale to plug valve orifices and fittings. Lastly, if deionized water from the SWS is used, the sterilizer jacket and heating elements will not require costly labor and downtime for cleaning. **ALWAYS ensure that the SWS is used for every fill-up to the WRS to keep minerals out of the entire system.**

Heater elements used without
deionized water
(Significant scale buildup)



Heater elements used with
deionized water
(No scale buildup)



ROUTINE STARTUP CHECKLIST

CHECK	OPERATION
	1. Remove and clean the chamber drain screen. (Inspect O-ring for potential damage on S/N's after AFS-0203. Replace with spare from SAB if necessary).
	2. Ensure chamber and jacket vent valves are closed.
	3. Flip the control power switch to the "ON" position.
	4. Fill the jacket with water to the HIGH mark using the WRS. NOTE: Never add water to the sterilizer during a cycle. This will cause the jacket to cool off, lose pressure, and alarm.
	5. Ensure the water level in the WRS is at, or near, the HIGH mark. If not, add water using the SWS.
	6. Run an IUSS cycle to warm up the chamber. NOTE: It is critical to run this warmup cycle to ensure successful completion of the Bowie-Dick test.
	7. Run a Bowie-Dick test per AAMI standards to ensure that air removal during the preconditioning phase is functioning properly.
	8. Proceed with a normal sterilization cycle as needed.

WARNING: Run a VACUUM LEAK TEST on a periodic basis per AAMI standards or at least weekly and always after any transport, relocation, or maintenance. If the VACUUM LEAK TEST FAILS, call a qualified maintenance technician to troubleshoot.

ROUTINE SHUTDOWN CHECKLIST

CHECK	OPERATION
	1. Add water to the jacket to the HIGH mark. This will help (1) cool down the jacket and (2) ensure that the jacket is full of water and ready to run again when needed. Also, “top off” the WRS water level to the HIGH mark using the SWS if needed.
	2. Leave the chamber door latched but not tightened to prevent a vacuum from being created in the chamber during cooldown. To break a vacuum in the chamber and open the door, press the “VENT” button on the control panel touch screen.
	3. Turn OFF SMU control power switch. <i>DO NOT</i> open the jacket vent valve. NOTE: As the SMU cools down, the steam in the jacket will condense, resulting in a deep vacuum. This condition is not a problem and will not cause any damage to the SMU. In fact, this is a <u>recommended practice</u> since relieving the vacuum by opening the jacket vent valve will allow air to enter the jacket. Keeping air out of the jacket will enable the next cycle to operate more efficiently. Air is the enemy of effective sterilization.

WARNING: If freezing temperatures are possible around the sterilizer, all water from the SMU, WRS, and SWS must be drained to prevent possible freezing and damage to the pressure vessel, pump, SWS housing, or other components. Reference Section 3.7 for information on draining water.

DAILY OPERATOR CHECKLIST

CHECK	TASK
	1. Remove and clean the chamber drain screen (Inspect O-ring for potential damage on S/N's after AFS-0203. Replace with spare from SAB if necessary).
	2. Wipe the chamber interior surfaces and shelves. WARNING: Do not allow any contaminants to go down the chamber drain and into the WRS.
	3. Look and listen for possible water and steam leaks.
	4. Verify that the cooling fans in the SMU (qty: 1) and the WRS (qty: 2*) are running. NOTE: On S/N's after AFS-0236, there is only 1 cooling fan mounted to the Back Panel of the WRS.
	5. Monitor water levels in the SMU jacket and WRS. NOTE: When the SMU jacket is at the HIGH mark, the WRS water level should be at or near the HIGH mark also. REMEMBER: Always use the SWS when adding water.
	6. Listen for any abnormal sounds during operation. Notify a qualified maintenance technician if there is a concern.

FDA-REQUIRED WATER CHANGEOUT

**EVERY 14 DAYS OR 100 CYCLES
(WHICHEVER OCCURS FIRST)**

CHECK	TASK
	<ol style="list-style-type: none">1. Clean the SMU chamber thoroughly using a mild detergent approved for use with aluminum.<ol style="list-style-type: none">a. Disconnect the condensate hose (red-tagged) at the WRS and place the end into a bucket.b. Drain any cleaning water / mild detergent into the bucket.c. Flush the hose with fresh water and then reconnect the hose to the WRS.<p>WARNING: Do not allow any water or detergent to drain into the WRS.</p>
	<ol style="list-style-type: none">2. Drain all the water from the SMU jacket by following the Jacket Blowdown Procedure in Section 4.1.2.<p>WARNING: To avoid a potential burn hazard, ensure the high-temperature drain hose is used.</p>
	<ol style="list-style-type: none">3. Drain the WRS by attaching the drain hose and opening the drain valve.
	<ol style="list-style-type: none">4. SWS maintenance:<ol style="list-style-type: none">a. Test the TDS level of the water coming out of SWS and replace the deionized water cartridge as needed. Reference Section 3.4.1 Testing Total Dissolved Solids and Section 4.3.4 SWS Cartridge Replacement.b. Test the chlorine level of the water coming out of the SWS Reference Section 3.4.3 Testing Free Chlorine Level. Water can foul and become discolored if not used regularly. Before each use, flush SWS until water is clear (2 minutes).
	<ol style="list-style-type: none">5. Refill the entire system with fresh potable water (Reference Section 2.5 – Water Supply Quality).
	<ol style="list-style-type: none">6. Run a VACUUM LEAK TEST.

3.4.1 Testing Total Dissolved Solids (TDS)

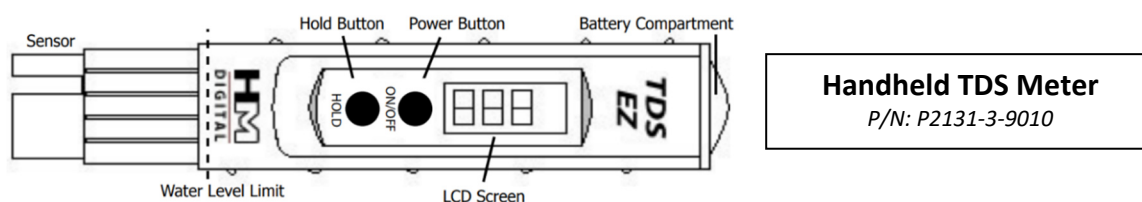
Using the Handheld TDS Meter, test the SWS outlet water stream every time the WRS is refilled (e.g., every 14 days or 100 cycles, whichever occurs first). Follow the instructions below.

Cartridge Replacement Criteria: If SWS outlet water TDS is ≥ 15 ppm, replace the SWS DI Water Cartridge. If the TDS reading is < 15 ppm, the SWS can be used as normal.

NOTE: If the feedwater is of poor quality and has a high TDS level, a brand-new cartridge may result in a TDS reading of greater than 15 ppm. To improve the TDS reading:

1. Improve incoming water quality.
2. Use SWS's in series to lower the TDS level before filling WRS.
3. Using a collection bucket or Jerry can, reprocess the water twice through the SWS before filling the WRS

NOTE: The meter is not water-tight. Do not dip the meter beyond the water level limit.



TDS Handheld Meter Calibration Check (every 6 months):

Immerse the meter into distilled water and verify it reads ≤ 5 ppm. If it reads > 5 ppm, either the distilled water could be contaminated, or TDS Meter is out of calibration and should be replaced.

Taking a TDS Measurement:

1. Remove the protective cap.
2. Turn the TDS Meter ON.
3. Collect a sample of SWS outlet water in a clean container.
4. Immerse the Meter into the sample up to the Water Level Limit.
5. Lightly stir the Meter in the water to dislodge any air bubbles.
6. Wait until the reading stabilizes and then press the HOLD button. The value displayed is the TDS Level of the water.

NOTE: Be sure to turn the TDS Meter OFF before storage to preserve the battery.

3.4.2 SWS Deionized Water Cartridge Capacity

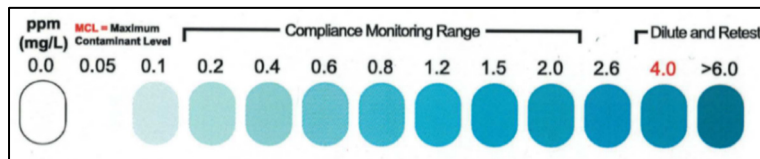
The amount of deionized water that the SWS can produce depends on the concentration of Total Dissolved Solids (TDS) of the supply water. For example, very hard water might have 425 ppm TDS, while relatively soft water might have 50 ppm TDS. The table below shows the approximate capacity in gallons of deionized water that the SWS can produce for varying supply water TDS levels.

	←Soft→		Hard	←Very Hard→	
Supply Water TDS (ppm)	0	50	120	255	425
SWS Capacity until Cartridge replacement (Gal)	1850	633	264	124	74

3.4.3 Testing Free Chlorine Level

Free chlorine is the available chlorine found in water to disinfect the water from contaminants, which prevents the water from fouling. It should be noted that free chlorine in water will completely evaporate within 24 hours and the evaporation rate increases when the water is exposed to the atmosphere. Additionally, trace amounts of free chlorine will be filtered out through the SWS Deionizing (DI) cartridge.

Using the free chlorine test strips provided in the SAB, test the supply water and SWS outlet water stream every time the SMU jacket and WRS are drained and refilled (e.g., every 14 days or 100 cycles, whichever occurs first). Follow the instructions listed on the chlorine test strip container to test the Free Chlorine Level.



Chlorine Test Strip

P/N: P2131-3-9007

Test the supply water and outlet water stream as shown below:



FDI's recommended Free Chlorine Levels:

	← Free Chlorine Level Range →	
Supply Water (ppm)	0.5	2.6
SWS Outlet Water Stream (ppm)	≥ 0.2	

1. If the SWS outlet water stream reads < 0.2 ppm, flush the SWS for another 2 minutes. If the test strip still reads < 0.2 ppm, this is an indication that the supplied water may not contain enough free chlorine.
2. If the supply water reads < 0.2 ppm, it may be necessary to adjust the treatment of the source water.
3. If Steps 1 and 2 have been trialed and the SWS outlet water stream continues to read < 0.2 ppm, the P2131 may still be filled and operated. The efficacy of the P2131 is not impacted by free chlorine levels.

Section 3.5 Operational Situations and Responses

SMU – Testing Related Situations

What do you do if ...	Response
A biological indicator fails but the cycle ran successfully with no alarms?	Reprocess per latest edition of ANSI/AAMI ST79.
The Bowie-Dick Test fails?	Reprocess per latest edition of ANSI/AAMI ST79. Was a warm-up cycle (IUSS) run to ensure that the chamber was heated up? If NO, then run the Bowie-Dick test again. If YES, then call a qualified maintenance technician to troubleshoot.
The Vacuum Leak Test fails?	Take the sterilizer out of service and contact a qualified maintenance technician who will use the Vacuum Leak Test troubleshooting guide in Section 4.3.14.

SMU – Cycle and PLC Related Situations

What do you do if ...	Response
The unit shuts off and emits a sustained alarm tone?	Turn the SMU OFF and disconnect power. Contact a qualified maintenance technician to troubleshoot the system.
You experience a power failure during operation?	Flip the control power switch to the OFF position. When the power returns, flip the control power switch ON. If the power outage was short, there will still be pressure in the jacket and pressure or vacuum in the chamber. Press “CONFIRM” on the “SETUP” screen, then press “VENT.” This will vent the pressure or vacuum in the chamber. After venting, open the door and reprocess the load per AAMI ST79 standards.
You want to stop a cycle?	Press “ABORT.”
The touch screen will not accept a command or seems to be “lost” and not functioning correctly?	Flip the control power switch to OFF, wait 5 seconds, and then flip it back ON. Restart the cycle.
The cycles are taking a lot longer than usual?	Allow the WRS water to cool. In a hot environment the cycles may take longer because the WRS water may be hot which effects the eductor performance.
You forgot to record a previous cycle?	From the “Main Menu”, press “Log.” On the “Log” screen you can view previous results by using the left-arrow button.
You turn ON the sterilizer and get a low battery error while the PLC is booting up.	Contact a qualified maintenance technician to have the battery replaced according to the Battery Replacement Procedure found in Section 4.3.16.
The PLC screen responds slowly when the screen is pressed.	Contact a qualified maintenance technician to have the battery replaced according to the Battery Replacement Procedure found in Section 4.3.16.

SMU – Water and Steam Related Situations

What do you do if ...	Response
You hear or see a steam leak somewhere other than the door?	If it is safe to do so, turn the control power switch OFF and allow the sterilizer to cool and depressurize. Contact a qualified maintenance technician.
You hear or see a steam leak at the door?	If it is safe to do so, wait for the cycle to finish and then inspect the door frame and door gasket for any debris that could prevent a good seal. Closely inspect the gasket for any damage such as nicks or cuts. Replace it if needed. If there is no damage, then tighten the door a little tighter on the next cycle.
You get a low water alarm?	Add water to the SMU from the WRS, close and tighten the chamber door, press "RESET," and restart the cycle. Also, recheck level in WRS after pumping and refill using the SWS if needed. It is best to run the WRS at the HIGH water mark (when the jacket is at the HIGH mark).
The jacket is overfilled with water?	Turn the sterilizer OFF and let it cool down and depressurize. With zero pressure on the jacket, attach the high-temperature hose and drain enough water out of the jacket to bring the level down to the HIGH mark on the sight gauge. Close the drain valve and turn the sterilizer back ON.
The jacket fills with water, but VERY slowly?	Contact a qualified maintenance technician for further diagnosis and repair on the WRS pump.
The jacket does not refill when switch on WRS depressed?	Verify the water level in the WRS, adding water through the SWS if necessary. Ensure that the power cord is plugged into the WRS and that the power switch is in the ON position. If the problem continues, contact a qualified maintenance technician for further diagnosis and repair.
The water level in jacket drops when sitting idle and pressurized?	The check valve at the back of SMU on recovered water line from WRS could be leaking. Contact a qualified maintenance technician to replace the check valve.
The SMU seems to be using more water than normal during each cycle?	The check valve at the back of SMU on the recovered water line from WRS could be leaking. Additionally, the steam trap could be hung open or damaged. Contact a qualified maintenance technician to inspect/replace the check valve and/or the steam trap.
The Pressure Safety Valve opens and releases steam?	Contact a qualified maintenance technician. If it is safe, turn the sterilizer OFF and disconnect the incoming power.
There is a lot of water around the sterilizer?	The source of the water should be identified immediately. Inspect the hose connections between the SMU and the WRS. Use a flashlight to inspect and locate the leak. If needed, de-energize and de-pressure the sterilizer, remove the side panels and inspect all fittings closely.
White/Tan residue in chamber	Dirty and/or hard water used. SWS not used. Possible cracked heater element. Inspect heaters and replace if needed. (See Section 4.3.10)

What do you do if ...	Response
Water is seen entering the SMU sight glass through the top during jacket fill-up	Contact a qualified maintenance technician to inspect and clean the Liquid Level Switch and Sight Glass plumbing. Address any blockages or issues found.

SMU – General Situations

What do you do if ...	Response
There is a vacuum in the jacket at startup?	No response needed. This is normal. The sterilizer can be turned on as usual.
There is algae in the sterilizer sight glass?	No response needed. Algae forms due to heat and light. It is normal and will not affect sterilization. To clean the sight glass, follow the procedure found in Section 4.3.3.
The chamber door will not open due to vacuum on the chamber?	Press “VENT” on the “Main Menu” or the “Log” screen. If you still cannot open the door, open the chamber vent valve in the back of the SMU to vent the chamber.
You hear an abnormal sound?	Take the sterilizer out of service and contact a qualified maintenance technician.
During exposure, the two pressure gauges are different?	One of the gauges is likely malfunctioning. Contact a qualified maintenance technician.
The chamber is failing to pull vacuum during pre-vac or drying?	Contact a qualified maintenance technician.

WRS and SWS – General Situations

What do you do if ...	Response
You hear the WRS pump start and stop intermittently or completely shut down?	The low water level switch may be activated. With the jacket water level at the HIGH mark, add water to the HIGH mark on the WRS using the SWS. Also, check the WRS power cable connection.
The WRS is running for seemingly no reason? <i>OR</i> The WRS keeps running after the alarm is RESET?	Close and tighten the door because the WRS may be trying to vent the chamber. To do so it must pull a very slight vacuum, which it cannot do with an open chamber door.
The WRS is empty and there is a lot of water in the chamber when the door is opened?	A vacuum in the chamber has pulled water up from the WRS into the chamber. Contact a qualified maintenance technician to inspect the steam trap check valve and the eductor check valve in the WRS for debris and clean/replace as needed.
The SWS is not available?	Locate another SWS. Do not add water to the WRS except through a SWS.

3.6 Alarm Code Troubleshooting Guide

WARNING: Service and maintenance work must be performed by qualified personnel only.

ALARM CODE	POSSIBLE CAUSES	CORRECTIVE ACTION
Sustained Alarm Tone & PLC Off	Liquid Level Switch Malfunction & Unit run with low or no water	Turn the SMU OFF and disconnect power. Inspect Liquid Level Switch. Does float move freely? Electrical continuity of Liquid Level Switch with water? No continuity without water? Replace liquid level switch or fix root cause of the malfunction. Re-qualify the switch per Operational Qualification (OQ) of the Liquid Level Switch before placing the unit back into service. See Section 3.1.
	Plug / debris in Liquid Level Switch Plumbing & Unit run with low or no water	If Liquid Level Switch is functional, inspect plumbing that leads to switch, including the heater flange tees, the hoses and any other fittings. Remove blockage and flush hoses. Re-qualify the switch per Operational Qualification (OQ) of the Liquid Level Switch before placing the unit back into service. See Section 3.1.
	HTS-1 RTD Sensor Failure	Remove right-side panel. Inspect HTS-1 INPUT LED and STATUS SCREEN to determine if there is an input failure. INPUT LED will turn red and STATUS SCREEN will display "BROKEN WIRE".
01 Cycle Aborted	Operator pressed Abort button	N/A
02 Low Water Level	Water level in jacket low	Add water to the jacket from the WRS, close and tighten the chamber door, press "RESET," wait for the jacket to heat up, and restart the cycle. Also, recheck level in WRS after pumping and refill if needed. Keep level in WRS at the HIGH mark when jacket water level is at its HIGH mark.

ALARM CODE	POSSIBLE CAUSES	CORRECTIVE ACTION
03 Jacket Warmup Slow	Jacket manual vent valve open Low ambient temperatures Heater element failure Scale buildup on heater elements and jacket	Close jacket vent valve. Warm up ambient conditions to 40°F, if possible. Contact a qualified maintenance technician to inspect and replace heater element. Contact a qualified maintenance technician to inspect heaters and jacket walls and clean as needed. Ensure SWS is being used on every water refill.
04 Long Heatup	Steam leak Faulty steam trap Resistance Temperature Detector (RTD) or RTD transmitter failure Multiple Heater element failure	Inspect door gasket and chamber fittings for steam leaks. Ensure trap is working properly. If steam trap is failed closed, condensate will pool in chamber. If steam trap fails open, steam will flow to the WRS water tank and make a loud popping noise or use more water than normal. Replace as needed. Contact a qualified maintenance technician to inspect RTD and RTD transmitter for physical damage, loose wires, broken communication cable to PLC. Compare temperature versus pressure on STATUS SCREEN. Replace as needed. Contact a qualified maintenance technician to remove heater elements, inspect/test, and replace as needed.

ALARM CODE	POSSIBLE CAUSES	CORRECTIVE ACTION
05 Long Exposure Time	Steam leak	Inspect door gasket and chamber fittings for steam leaks.
	Faulty steam trap	Ensure trap is working properly. If steam trap is failed closed, condensate will pool in chamber. If steam trap fails open, steam will flow to WRS water tank and make a loud popping noise or use more water than normal. Replace as needed.
	RTD or RTD transmitter failure	Contact a qualified maintenance technician to inspect RTD and RTD transmitter for physical damage, loose wires, broken communication cable to PLC. Compare temperature versus pressure on STATUS screen. Replace as needed.
	Condensate drain screen plugged	Remove and clean screen.
	Sterilizer not tilted correctly	Verify correct tilt. Condensate should drain easily to front chamber drain.
	Low ambient temperatures	Warm up ambient conditions to 40°F, if possible.
	Multiple Heater element failure	If everything else has been checked, contact a qualified maintenance technician to remove heater elements, inspect/test, and replace as needed.

ALARM CODE	POSSIBLE CAUSES	CORRECTIVE ACTION
06 Insufficient Vacuum	Loose vacuum/exhaust hose fittings (white-tagged hose)	Inspect O-rings at each end and re-tighten the hose.
	Pump not operating in WRS	Check WRS water level, power cord, and power switch.
	Hot water in WRS	Ensure both WRS fans are running when pump is ON. Ensure water level is at least 1/2 full. Too little water will tend to overheat and cause low eductor performance.
	Eductor problem in WRS	Contact a qualified maintenance technician to inspect eductor for leak or worn/broken nozzle inside eductor. Replace if needed.
	Vacuum valve not open far enough	Contact a qualified maintenance technician to inspect solenoid valve and replace if needed. NOTE: Reference Appendix A.5 Vacuum Leak Test Troubleshooting Guide for more help on troubleshooting a potential leak in the system.
07 Chamber Pressure High	Jacket pressure high	Reference alarm code 09 Jacket Pressure High.

ALARM CODE	POSSIBLE CAUSES	CORRECTIVE ACTION
08 Chamber Pressure Low	Gasket leak at door	Inspect for leak with pressure and identify location. Inspect gasket for debris or cut. Replace as needed.
	Manual chamber vent valve leaking	Contact a qualified maintenance technician to inspect vent valve and replace as needed.
	Faulty steam trap	Ensure trap is working properly. If steam trap is failed closed, condensate will pool in chamber. If steam trap fails open, steam will flow to WRS water tank and make loud popping noise or use more water than normal. Replace as needed.
	Vacuum/Exhaust valve leaking	Contact a qualified maintenance technician to inspect outlet of valve for leaking.
	Sterilize valve failure – not opening properly	Contact a qualified maintenance technician to inspect solenoid valve and replace if needed.
	Condensate drain screen plugged	Remove, clean, and replace screen.
		NOTE: Also reference causes of Alarm Code 05 Long Exposure Time.

ALARM CODE	POSSIBLE CAUSES	CORRECTIVE ACTION
09 Jacket Pressure High	Air compressed in jacket during water fill	Turn OFF sterilizer and allow jacket to cool and depressurize. Open jacket vent valve to bring pressure to zero. Close jacket vent valve. Turn sterilizer back ON.
	RTD or RTD transmitter failure	Contact a qualified maintenance technician to inspect RTD and RTD transmitter for physical damage, loose wires, broken communication cable to PLC. Compare temperature versus pressure on STATUS screen. Replace as needed.
	SMU tilt is not steep enough	Shim the rear of the sterilizer higher to improve condensate flow to the chamber drain.
	Condensate drain screen plugged	Remove and clean screen. Replace after cleaning.
	Solid state heater relays leaking current	Contact a qualified maintenance technician to test relay for leakage and replace as needed.
	Jacket pressure transmitter failure	Open Chamber Door and compare digital pressure readout on STATUS screen on PLC to analog gauge on front panel. Jacket Pressure reading \approx 28 psig and Chamber Pressure Reading \approx 0 psig.
10 Long Vent Time	Barometric Pressure Not Zeroed	On "CONFIRM SETUP" screen, zero barometric pressure. This is only required during setup at a new location.
	Door not tightened during manual VENT	Tighten door.
	Vacuum break valve failure (not opening far enough)	Contact a qualified maintenance technician to inspect and test both valves. Replace as needed (Note flow direction. Arrows on valve should point toward each other ($\rightarrow \leftarrow$)). Open chamber vent valve to access chamber.
	Vacuum/exhaust valve failure (not opening far enough) if on IUSS cycle	Contact a qualified maintenance technician to inspect and test valve. Replace as needed. Open chamber vent valve.

ALARM CODE	POSSIBLE CAUSES	CORRECTIVE ACTION
11 Long Dry Time	Leak in chamber or associated fittings and valves, including vacuum hose to the WRS	Contact a qualified maintenance technician to inspect solenoid valves and manual valves for leaks. Inspect fittings for leaks. Inspect vacuum hose (white-tagged hose) to WRS for leaks. Repair as needed.
12 Vacuum Test Failed	Leak in chamber or associated fittings and valves, including vacuum hose to the WRS	<p>Contact a qualified maintenance technician to inspect solenoid valves and manual valves for leaks. Inspect fittings for leaks. Inspect vacuum hose (white-tagged hose) to WRS for leaks. Repair as needed.</p> <p>NOTE: Reference Appendix A.5 Vacuum Leak Test troubleshooting guide for more help on troubleshooting a potential leak in the system.</p>
13 Fuse F3 - Inputs	<p>Overcurrent</p> <p>Faulty fuse</p>	<p>Contact a qualified maintenance technician to correct cause of overcurrent and replace fuse F3.</p> <p>Contact a qualified maintenance technician inspect and replace fuse F3.</p>
14 Fuse F5 - Outputs	<p>Overcurrent</p> <p>Faulty fuse</p>	<p>Contact a qualified maintenance technician to correct cause of overcurrent and replace fuse F5.</p> <p>Contact a qualified maintenance technician to inspect and replace fuse F5.</p>
15 Door Opened Alarm	<p>Door opened during a cycle</p> <p>Fiber optic door switch failure/fault</p>	<p>Reset and rerun cycle.</p> <p>Contact a qualified maintenance technician to inspect and replace fiber optic cable and/or mini-beam sensor or adjust fiber optic cable at door.</p>

ALARM CODE	POSSIBLE CAUSES	CORRECTIVE ACTION
16 Chamber High Temperature	RTD or RTD transmitter failure	Contact a qualified maintenance technician to inspect RTD and RTD transmitter for physical damage, loose wires, broken communication cable to PLC. Compare temperature versus pressure on STATUS screen. Replace as needed.
	Faulty steam trap	Ensure trap is working properly. If steam trap is failed closed, condensate will pool in chamber. If steam trap fails open, steam will flow to WRS water tank and make loud popping noise or use more water than normal. Replace as needed.
	Air in jacket	Reset and rerun cycle.
	Condensate drain screen plugged	Remove and clean screen. Replace after cleaning.
	Sterilizer not tilted correctly	Verify correct tilt. Water should drain easily to front chamber drain.
	Solid state heater relays leaking current	Contact a qualified maintenance technician to test relay for leakage and replace as needed.
17 Chamber Sensor	RTD or RTD transmitter failure	Contact a qualified maintenance technician to inspect RTD and RTD transmitter for physical damage, loose wires, broken communication cable to PLC. Compare temperature versus pressure on STATUS SCREEN. Replace as needed.
	Chamber pressure transmitter failure	Contact a qualified maintenance technician to inspect and replace sensor and/or transmitter.
18 Processor Error	Program corrupted	Contact a qualified maintenance technician to download new program, and/or replace PLC.
19 Exposure Timer	Real-time clock error	Contact a qualified maintenance technician to replace battery in PLC. Reference procedure in Section 4.3.16 - Battery Replacement Procedure.
20 Dry Timer	Real-time clock error	Contact a qualified maintenance technician to replace battery in PLC. Reference procedure in Section 4.3.16 - Battery Replacement Procedure.

ALARM CODE	POSSIBLE CAUSES	CORRECTIVE ACTION
21 Temperature Sensor	Large RTD deviation, RTD or RTD transmitter failure	Contact a qualified maintenance technician to inspect RTD and RTD transmitter for physical damage, loose wires, broken communication cable to PLC. Compare RTD-1 versus RTD-2 on "STATUS" screen. Replace as needed.
22 High Exposure Temperature	RTD or RTD transmitter failure Faulty steam trap Condensate drain screen plugged Sterilizer not tilted correctly Solid state heater relays leaking current	Contact a qualified maintenance technician to inspect RTD and RTD transmitter for physical damage, loose wires, broken communication cable to PLC. Compare temperature versus pressure on STATUS SCREEN. Replace as needed. Ensure trap is working properly. If steam trap is failed closed, condensate will pool in chamber. If steam trap fails open, steam will flow to WRS water tank and make loud popping noise or use more water than normal. Replace as needed. Remove, clean, and replace screen. Verify correct tilt. Water should drain easily to front chamber drain. Contact a qualified maintenance technician to test relay for leakage and replace as needed.
23 Jacket Sensor	Jacket pressure transmitter failure	Contact a qualified maintenance technician to inspect and replace transmitter.

Section 3.7 Checklist for Transport and/or Storage

CHECK	OPERATION
	1. Ensure that the water in the WRS is at the HIGH mark (add some water if needed using the SWS). Ensure water in the SMU is at the HIGH mark.
	2. Remove the top panel from the WRS.
	3. Pour 1/2 gallon of chlorine bleach (3-6% sodium hypochlorite) into the breather port of the WRS water tank only. Reference Section 4.5 for location. CAUTION: Do not pump water into the SMU while bleach solution is in the WRS. Disinfecting clean is for the WRS only.
	4. Run a Textile 4/5 cycle. The cycle will circulate water in the WRS to ensure effective disinfection. Drain the WRS and refill with deionized water from the SWS. Run a second Textile 4/5 cycle. This will help rinse any remaining cleaning solution.
	5. Perform the Jacket Blowdown Procedure in Section 4.1 to remove any contaminants that may have accumulated in the jacket. Allow the SMU to cool to ambient temperature. Remove the drain hose. WARNING: Do not blow out with compressed air.
	6. Confirm the SMU power switch and the WRS power switch are in the OFF position.
	7. Disconnect the WRS power cord and store in SMU endcap.
	8. Disconnect the SMU power cord and store in endcap.
	9. Ensure the jacket and chamber are at 0 psig. The jacket and chamber vent valves should be left open for storage.
	10. Remove the shelves and place in the SAB for transport.
	11. Remove the chamber drain screen and clean. Place the drain screen in the SAB for transport for S/N's AFS-0001 through AFS-0203. On S/N's after AFS-0204, the drain screen can be left in chamber.
	12. Remove the three hoses between WRS and SMU and install the caps. Store hoses inside the SAB.
	13. Remove shims from under SMU and store inside the side pocket of the SAB.

Continued on next page

Checklist for Transport and/or Storage (continued)

CHECK	OPERATION
	14. Pull WRS out from under SMU.
	<p>15. Connect high-temperature drain hose to WRS Tank Drain Connection. Open valve and allow WRS to drain fully. Lift and tilt WRS repeatedly to ensure all water is drained. The Tank Drain Valve should be left open for storage. Remove the drain hose.</p> <p>WARNING: Do not blow out with compressed air.</p>
	<p>16. For S/N's AFS-0001 through AFS-0236, loosen the four panel latches and remove WRS front panel. Open the petcock valve (do not remove completely) on bottom of pump and allow to drain fully. Tilt the WRS back and forth repeatedly to ensure all water is drained. Close petcock valve and reinstall panel.</p> <p>For S/N's after AFS-0236, open the Pump Drain Valve. Tilt the WRS back and forth repeatedly to ensure all the water is drained. The Pump Drain Valve must be left open for storage. Open the Water Fill Valve for storage.</p> <p>WARNING: Water remaining in pump could freeze and crack the pump or cause it to seize.</p>
	<p>17. For S/N's AFS-0001 through AFS-0236, remove Back Lower Panel and the black Heater Assembly Cover (reference Section 4.3.17) and then drain the Heater Flange Tees by removing the two Tee Caps on the back of the SMU (reference Section 3.2 - Controls and Indicators – Rear View of SMU for location). Store the caps by screwing them onto the Tee Cap Retainers on the back of the unit <u>finger tight</u>. Reinstall the Heater Assembly Cover and Back Lower Panel</p> <p>For S/N's after AFS-0236, the Heater Flange Tees no longer exist, and the unit will naturally drain through the Jacket Drain Valve.</p>
	18. Lift and tilt the front of the SMU to ensure all water drains out.
	19. After the jacket is fully drained, the Jacket Drain Valve must be left open for storage.
	20. Store the high-temperature drain hose in the SAB. Ensure the hose is completely drained of water.

Checklist for Transport and/or Storage (continued)

CHECK	OPERATION
	21. Verify that all items are in the SAB and then place the SAB inside the chamber of the SMU. Close and tighten the chamber door. Leave the door snug but not fully tightened.
	22. Reference steps 1 through 9 from Section 3.1 - Installation and Setup to fold up endcaps on SMU. Using light oil, lubricate endcap hinges and threaded portion of endcap knobs.
	23. Perform TDS water quality test to ensure SWS is correctly deionizing the water. Replace cartridge as needed. See Section 3.4.1.
	<p>24. Remove the inlet and outlet hoses on SWS. Remove the blue housing and turn upside down to allow the water to drain <u>completely</u> from the inlet/outlet. Place back into frame, connect outlet hose, and ensure manual valve is closed. Connect manual pump outlet hose to inlet of SWS. Wrap and secure all hoses for transport.</p> <p>NOTE: On S/N's after AFS-0255, all hoses can be stored in the SWS frame. Release the Handle Latches to fold the handle down and store all hoses inside the frame. Close the Handle and secure the two Handle Latches.</p>

Section 3.8 Consumable Items

The following operator supplies are typically consumed during standard use of the P2131 system. For replacement parts, see Section 4.4.

ITEM	DESCRIPTION	PART NUMBER
1.	VERIFY™ REUSABLE PROCESS CHALLENGE DEVICE	P2131-1-9003
2.	VERIFY™ CLASS 5 CHEMICAL INTEGRATOR (2,000/BOX)	P2131-1-9004
3.	VERIFY™ EXTENDED CYCLE TUBE (50/BOX)	P2131-1-9005
4.	VERIFY™ BOWIE DICK TEST STRIP (100/BAG)	P2131-1-9006
5.	3M 1296 - BIOLOGICAL PROCESS CHALLENGE DEVICE (25/BOX)	P2131-1-9010
6.	3M 1243 - CLASS 5 CHEMICAL INTEGRATOR (100/BAG)	P2131-1-9011
7.	3M 1292 - BIOLOGICAL INDICATOR (50/BOX)	P2131-1-9012
8.	3M 1233L - BOWIE DICK TEST PACK (30/BOX)	P2131-1-9013
9.	TEST STRIPS, WATER CHLORINE LEVEL (PACKS OF 50)	P2131-3-9007
10.	CARTRIDGE, SWS DEIONIZED WATER (PACK OF 6)	P2131-3-9008

NOTE: To purchase consumables, contact FDI at 865-408-0100 or sales@fortdefianceind.com

SECTION 4 – MAINTENANCE

4.1 Preventive Maintenance

WARNING: Ensure that AAMI standards are followed for qualification testing after maintenance or repairs. Reference Post-Maintenance Checklist for checkout procedure.

WARNING: When not in use, the P2131 SMU and the WRS should be drained completely to prevent potential growth of biological matter. To drain water, lift and gently rock the SMU or WRS back and forth. Do not use compressed air to blow out water.

WARNING: The P2131 sterilizer has a pressure vessel that has been ASME B&PV code stamped. It is a violation of federal code to replace the main door plate or make any repairs to the pressure vessel. All repairs to the pressure vessel, including the door plate, must be made BY FDI.

WARNING: Replacement parts should be sourced from FDI. Use of unauthorized parts could be of inferior quality, configuration, or specification and could compromise the safety and/or efficacy of the sterilizer and will void the warranty.

4.1.1 Preventive Maintenance Summary

Frequency	Task	Section
2 Weeks, or 100 Cycles (whichever comes first)	1. FDA-Required Water Changeout	3.4
2 Months	1. Pressure Safety Valve Test 2. Jacket Blowdown	4.1.2
6 Months, or 1300 Cycles	1. Replace the HEPA Filter 2. Lubricate Chamber Doorpost Threads 3. Inspect Electrical Box Inlet Air Filter 4. Inspect Electrical Box Cooling Fan Air Filter 5. Inspect Heat Exchanger in WRS 6. Inspect Heat Exchanger Fan in WRS 7. Inspect WRS and SMU Electrical Wiring 8. Ensure Jam Nuts are tight 9. Ensure adequate replacement parts 10. Retorque Doorpost Screws 11. Retorque Heater Plate Nuts 12. Check calibration of Handheld TDS Meter	4.1.3 3.4.1
12 Months	1. WRS Disinfecting Clean 2. Heater Flange Tee Inspection and Cleanout NOTE: For S/N's after AFS-0236, this procedure is no longer required. 3. High Temperature Limit Switch Check 4. WRS K4 Relay and Liquid Level Switch Check 5. Inspect SMU Fill Check Valve & WRS Fill Valve 6. Retorque WRS Pump Head Screws 7. WRS Breather & PSV Inspection	4.1.4

NOTE: These procedures do not apply for units in storage. Perform the outlined Maintenance Procedures only when the unit is considered operational.

4.1.2 2-Month Preventive Maintenance

Pressure Safety Valve Test

(NOTE: this procedure also conducted on 1st startup after storage)

CHECK	TASK
	<p>WARNING: Do not pull the pin on the PSV while the unit is under pressure. Hot Steam will exit the valve and can cause injury.</p> <ol style="list-style-type: none">1. With the jacket pressure at atmospheric pressure (e.g., 0 psig), pull the pressure safety valve (PSV) pin on the rear of the SMU to ensure the valve is not stuck and the pin moves freely.2. Then, turn the sterilizer ON and allow to fully heat up. Inspect the PSV to ensure there are no leaks.

Jacket Blowdown Procedure

CHECK	TASK
	<ol style="list-style-type: none">1. With the sterilizer completely setup and the jacket at normal operating pressure, connect the high-temperature drain hose to the jacket drain valve. CAUTION: The jacket drain valve is hot. To avoid a potential burn hazard, use heat resistant gloves to operate the valve and attach/remove the drain hose. CAUTION: To avoid a potential burn hazard, ensure the high-temperature drain hose is used to perform the jacket blowdown.
	<ol style="list-style-type: none">2. Relocate the shims to the front of the sterilizer to tilt the unit towards the jacket drain valve.
	<ol style="list-style-type: none">3. Ensure the outlet of the drain hose is positioned at a safe location. Securely anchor the drain hose outlet to prevent any hose whip that might occur from the hot water / steam flowing from the drain hose. CAUTION: Hot water and steam will flow from the outlet of the drain hose during blowdown. Do not attempt to hold the hose outlet by hand.
	<ol style="list-style-type: none">4. Turn OFF the SMU and disconnect Class L plug. Using heat resistant gloves, slowly open the jacket drain valve completely to perform a pressured blowdown of the jacket. This will remove any contaminants that have built up in the jacket.
	<ol style="list-style-type: none">5. Once the jacket pressure has reached 0 psig, the jacket blowdown is complete.
	<ol style="list-style-type: none">6. Return the sterilizer to the original tilt by returning the shims from the front to the back of the sterilizer.

4.1.3 6-Month Preventive Maintenance

EVERY 6 MONTHS OR 1300 CYCLES (WHICHEVER OCCURS FIRST)

WARNING: To avoid a potential electrical shock or burn hazard, be sure the sterilizer has been de-energized and depressurized prior to performing these tasks.

CHECK	TASK
	1. Replace the HEPA filter located under the SMU top panel. The HEPA filter is a safeguard against contamination during vacuum and should always be in good working condition.
	2. Lightly lubricate the chamber doorpost threads using high temperature (275°F) NLGI #2 grease.
	3. Inspect inlet air filter on right-hand side of SMU. If dirty, wash and reinstall.
	4. Inspect air filter on outlet of SMU electrical box cooling fan. If dirty, wash and reinstall. Remove the SMU top and right-hand side panel to access this filter.
	5. Inspect the heat exchanger in the WRS and clean if dirty.
	6. Apply power (120V/60Hz) to heat exchanger fan in WRS and ensure that it is functional. NOTE: Operation of this fan is normally hidden. NOTE: On S/N's after AFS-0236, there is a single fan mounted on the heat exchanger mounted on the Back Panel. Operation of this fan can be observed by checking for air flow during operation of the Sterilizer.
	7. Inspect wiring in SMU and WRS electrical boxes for loose wires, corrosion, or other concerns.
	8. Ensure jam nuts on the two front chamber mounts are tight. Also, ensure the rear chamber mounting bolts are tight.
	9. Ensure adequate replacement parts are in stock to ensure your mean-time-to-repair (MTTR) objectives can be met. Reference Section 4.4 and order parts as needed.
	10. Re-torque the 3 doorpost screws to 90 in-lbs.
	11. Remove Heater Assembly Cover and Heater Block Enclosure, re-torque the 8 heater plate nuts to 120 in-lbs. Inspect 3 heater wires before reinstalling the Heater Block Enclosure and Heater Assembly Cover. Reference Section 4.3.17 to remove Heater Assembly Cover.
	12. Check calibration of Handheld TDS Meter. See Section 3.4.1.

4.1.4 12-Month Preventive Maintenance

Disinfecting Clean of the WRS (FDA-Required)

CHECK	TASK
	1. Ensure that the water in the SMU and WRS are at the HIGH mark (add some water if needed using the SWS). Ensure water in the SMU is at the HIGH mark.
	2. Remove the top panel from the WRS.
	3. Pour 1/2 gallon of chlorine bleach (3-6% sodium hypochlorite) into the breather port of the WRS water tank only. Reference Section 4.5 for location. CAUTION: Do not pump water into the SMU while bleach solution is in the WRS. Disinfecting clean is for the WRS only.
	4. Run a Textile 4/5 cycle. The cycle will circulate water in the WRS to ensure effective disinfection. Drain the WRS and refill with deionized water from the SWS. Run a second Textile 4/5 cycle. This will help rinse any remaining cleaning solution.
	5. After completion of this cycle, drain the WRS completely.
	6. Refill the WRS with deionized water from the SWS.
	7. Run a Textile 4/5 cycle to rinse any remaining cleaning solution.
	8. Drain and refill the WRS with deionized water from the SWS.
	9. Reinstall the top panel on the WRS.

Heater Flange Tee Inspection and Cleanout

WARNING: To avoid a potential electrical shock or burn hazard, be sure the sterilizer has been de-energized, depressurized, and drained prior to performing these tasks.

***NOTE:** This procedure is no longer necessary for S/N's after AFS-0236.

CHECK	TASK
	1. Remove Back Lower Panel and Heater Assembly Cover (Reference Section 4.3.17)
	2. Remove the two Heater Flange Drain Caps. (Reference Section 3.2 Controls and Indicators – Rear View of SMU for location).
	3. Inspect the heater flange tees to ensure there are no blockages. CAUTION: Use eye protection when examining heater flange tees.
	4. If any blockages exist, use a small tool to break debris free and clean out the heater flange tees. Take care to prevent damage to the fittings.
	5. Replace heater flange drain caps. Tighten finger-tight and 1/4 turn.
	6. Reinstall Heater Assembly Cover and Back Lower Panel

High Temperature Limit Switch Check

CAUTION: High Voltage contacts exposed with the right-side panel removed. Electrical shock hazard when observing the HTS display while the SMU is ON.

CHECK	TASK
	1. Ensure the SMU is full of water. With the sterilizer OFF and <u>at room temperature</u> , remove the right-side panel of the SMU.
	2. Locate the High Temperature Limit Switch (HTS) display.
	3. Turn the SMU ON. Observe that the HTS display reads approximately room temperature. The temperature will begin to increase as the heaters start to energize.
	4. Once the unit is fully heated up (around 30 minutes), ensure the HTS display reads between 260 - 280°F. NOTE: This temperature range reflects variations due to altitude and is approximate.

WRS K4 Relay and Liquid Level Switch Check

CAUTION: High Voltage contacts exposed with the WRS Top Panel removed. Electrical shock hazard when using a multi-meter to check the K4 Relay and Liquid Level Switch.

CHECK	TASK
	1. Remove the Top Panel from the WRS.
	2. Connect power to the WRS from the SMU, but do not slide the WRS underneath the SMU or connect the white hoses.
	3. Turn the SMU and WRS on. <u>With the WRS empty</u> , use a multi-meter to check terminal #10 on S/N's AFS-0001 through AFS-0236 or terminal #14 on S/N's after AFS-0236 for 115 VAC.
	4. <u>With the WRS empty</u> , use a multi-meter to check for no continuity across terminal #1 and #5 on K4 Relay.
	5. <u>Fill the WRS</u> . Use a multi-meter to check terminal #10 on S/N's AFS-0001 – 0236 and terminal #14 on S/N's after AFS-0236 for 0 to 40 VAC.
	6. <u>With the WRS filled</u> , use a multimeter to check for continuity across terminal #1 and #5 on K4 Relay.

Inspect SMU Fill Check Valve & WRS Fill Valve

CAUTION: Burn Hazard. Hot water and/or steam can remain in the hose that will be removed below when it is disconnected.

CHECK	TASK
	1. Ensure the Sterilizer is fully setup and heated-up.
	2. Remove the Recovered Water from WRS Hose (Blue-tagged) from the SMU and WRS. CAUTION: Do not remove any other hoses. Check to ensure that no water is exiting the SMU Blue-tagged VCO fitting.
	3. Start an IUSS cycle, which will start the pump on the WRS. Check to ensure that no water drips from the WRS Blue-tagged VCO fitting.
	4. Abort the cycle and allow the SMU to vent.
	5. Verify that O-rings are in place and reconnect the hose.

Retorque WRS Pump Head Screws

CHECK	TASK
	1. Ensure the WRS is disconnected from the SMU and is accessible from all sides.
	2. Remove the Front Panel (panel closest to bulkhead end) to expose the motor.
	3. Using a 10 mm socket and torque wrench set to 108 in-lbs., torque the 4 pump head bolts (See Section 4.5 Interior Components Diagrams for location).
	4. Replace the Front Panel, reconnect the WRS, and verify proper operation of the WRS by pumping water into the SMU.

WRS Breather & PSV Inspection

CHECK	TASK
	1. Ensure the WRS is disconnected from the SMU and is accessible from all sides.
	2. Remove the Top Panel.
	3. Remove the Bleach Fill Port and Breather Plug (See Section 4.5 Interior Components Diagrams for location) and inspect that air can freely pass through the breather and that the breather is not clogged with debris.
	4. If necessary, clean the breather plug by using compressed air.
	5. Reinstall the breather plug.
	6. Pull the Tank Pressure Relief Valve ring (See Section 4.5 Interior Components Diagrams for location) and verify that the poppet moves freely and re-seats.
	7. Replace the Top Panel.

4.1.5 Post-Maintenance Checklist

(After any intrusive service work)

CHECK	TASK
	1. The unit is tilted for correct condensate drainage. Ensure the back of the unit is 1" higher than the front (approx. 4 shims).
	2. All hoses are connected.
	3. All electrical cables are connected.
	4. No loose parts or tools in the electrical panels.
	5. All panels are reinstalled.
	6. The water levels in the SMU and the WRS are both at the HIGH marks.
	7. The jacket vent valve, chamber vent valve, and both drain valves are closed firmly.
	8. The WRS is turned ON.
	9. All accessories are accounted for in the SAB and the SAB is properly stored.
	10. All shelves are in place.
	11. All alarms, repairs, and cycle count (found in "STATUS" screen) are documented.
	12. During a cycle, there are no steam leaks or water leaks.
	13. Cycle times are normal.
	14. Chamber vents correctly.
	15. Follow all applicable requirements in AAMI ST79 for post-maintenance performance qualification (e.g. IUSS warmup, Vacuum Leak Test, three successful Bowie Dick Tests).

4.2 Special Tools and Materials Required for Maintenance

The P2131 is specifically designed using components with standard sizing, allowing the system to be maintained and repaired using tools that are common to most maintenance technicians. These items are assumed to be readily available.

Only a few items would be considered necessary for maintaining this equipment that may be less readily available. These unique items are listed below.

1. Wrench, Torque (3/8" Square Drive, capable up to 150 inch-lbs.), (P/N: P2131-1-9015)
2. Grease, High Temperature (275°F), NLGI #2, (P/N: P2131-1-9016)
3. Bleach, Chlorine, 3-6% Solution, (P/N: P2131-2-9004)
4. Mallet, Soft, (P/N: P2131-1-9020)
5. Gloves, Heat Resistant, (P/N: P2131-1-9017)
6. Brush. Long, Thin Bottle-type, (P/N: P2131-1-9018)
7. Wrench, 11/16" Flare Nut, (P/N: P2131-1-9021)
8. Pigtail, WRS Power Cord, (P/N: P2131-2-4016) *NOTE: This is optional and allows the WRS to be setup to the side of the SMU for troubleshooting.*

4.3 Maintenance Procedures

WARNING: Maintenance work must be performed by qualified maintenance technicians.

Maintenance Videos

Please visit the FDI video channel for helpful and informative videos on the maintenance of the P2131 sterilizer. Scan the QR code below, click on the hyperlink (if you are using the electronic version of the Technical Manual), or enter the Web address listed to access these videos.

NOTE: This channel is updated frequently, so check back periodically to view new content.



<https://tinyurl.com/2kraxrf9>

Procedures Summary List:

Section	Procedure
4.3.1	Replacing the HTS-1 RTD Sensors
4.3.2	Disinfecting Clean for WRS
4.3.3	Cleaning the Sight Glass
4.3.4	Replacing the SWS Cartridge
4.3.5	Replacing the HEPA Filter
4.3.6	Replacing the Steam Trap
4.3.7	Replacing the RTD Sensor
4.3.8	Replacing the Chamber Door Gasket
4.3.9	Replacing the Chamber Doorpost O-Ring
4.3.10	Replacing Electric Immersion Heating Elements
4.3.11	Replacing the PLC
4.3.12	PLC Software Update
4.3.13	PLC Firmware Update
4.3.14	Vacuum Leak Test Troubleshooting
4.3.15	Door Switch Reprogramming
4.3.16	Replacing the PLC Battery
4.3.17	Removing Back Lower Panel and Heater Assembly Cover

4.3.1 Replacing the HTS-1 RTD Sensors

1. Turn OFF the SMU, disconnect power, and ensure pressure in the chamber and jacket is at 0 psig.
2. Remove the Back Lower Panel, Heater Assembly Cover, and Heater Block Enclosure by removing 10 pan head screws. (Reference Section 4.3.17)
3. Disconnect the 3 incoming heater wires by using 3/8" wrench to counter-torque and 3/8" socket to loosen nuts. Heater element nuts are torqued to 35 in-lbs.

S/N's AFS-0001 through 0286
Wiring Configuration



S/N's after AFS-0286
Wiring Configuration

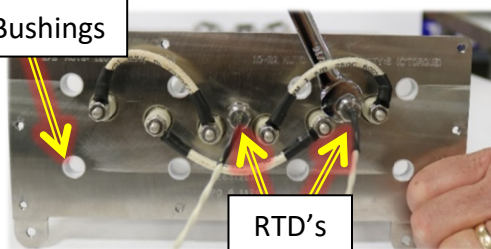


NOTE: Always reuse the blue isolation washers against heater plate when reinstalling heater plate.

4. Disconnect the white RTD Connector in bottom of heater box.
5. Remove 8 white heater stud caps (After S/N's AFS-0340).
6. Remove the 8 heater plate nuts with a 9/16 socket. Remove the lock, flat, and isolation washers. The heater plate nuts are torqued to 120 in-lbs.
7. Use a rubber mallet to pry the heater plate away from the heater flange.
8. Slide the Heater Element Assembly out of the jacket.
9. Compress the springs and slide the springs off the end of both RTD's.



Isolation Bushings



10. Remove both RTD's by loosening Swagelok nut and sliding out. Discard old RTD's.
11. Install new RTD's by inserting into Swagelok fitting and tightening nut finger tight then 1/4 turn. The long RTD is installed in the right fitting, on right leg of center heater element. The short RTD is installed in the center fitting, on left leg of center heater element.
12. On the long probe, compress and slide a spring to the center of the probe. On both the long and short probe, compress and slide the springs over the end of the RTD's until approximately 3/8" of the RTD probe extends beyond the spring.
13. Reinstall Heater Element Assembly by following steps 1-4 in reverse order. Ensure isolation bushings are reused. Ensure blue isolation washers are reused.

4.3.2 Disinfecting Clean for WRS

1. Ensure that the water in the WRS is at the HIGH mark (add some water if needed using the SWS).
2. Remove the top panel from the WRS.
3. Pour 1/2 gallon of chlorine bleach (3-6% sodium hypochlorite) into the breather port of the WRS water tank only (Reference Section 4.5). **CAUTION:** Do not pump water into the SMU while bleach solution is in the WRS. Disinfecting clean is for the WRS only. **NOTE:** On S/N's after AFS-0236, the breather also functions as the fill port and can be used for this procedure.
4. Run a Textile 4/5 cycle. The cycle will circulate water in the WRS to ensure effective disinfection. Drain the WRS and refill with deionized water from the SWS. Run a second Textile 4/5 cycle. This will help rinse any remaining cleaning solution.
5. After completion of this cycle, drain the WRS completely.
6. Refill with deionized water from the SWS.
7. Run a Textile 4/5 cycle to rinse any remaining cleaning solution.
8. Drain and refill with deionized water from the SWS.
9. Reinstall the top panel on the WRS.

4.3.3 Cleaning the Sight Glass

NOTE: Algae may form in the sight glass due to heat and light. It is a normal occurrence and does not affect sterilization.

CAUTION: Take care not to loosen the fittings that are in the sterilizer pressure vessel.

1. With the sterilizer OFF, de-energized and depressurized, open the jacket vent valve to completely vent the jacket.
2. Connect the high temperature drain hose to the drain connection. Then, open the jacket drain valve to drain the water from the jacket. Close this valve once all water has drained from the jacket.
3. Unscrew the 2 hex head fasteners on the front of the sight glass. Do not lose the O-rings.
4. Unscrew the top and bottom screws on the sight glass. Do not lose the O-rings.
5. Taking care that the glass cylinder does not drop out through the housing, remove the socket head set screws inside the sight glass. Slide the glass cylinder out of the housing.
6. Using soap, water, and a long brush, carefully clean the inside of the cylinder.
7. Slide the glass cylinder back into the housing and replace the socket head set screws.
8. With the O-rings in place, screw the top and bottom screws into the housing.
9. With the O-rings in place, position the sight glass on the back of the sterilizer and tighten the two hex head fasteners. **CAUTION:** Do not overtighten these fasteners since this is an O-ring seal.
10. Turn the sterilizer ON and refill the jacket to the HIGH mark (top off water level in WRS as well, using the SWS). Once filled, close the jacket vent valve.
11. Watch for steam leaks and water leaks as the jacket pressurizes.

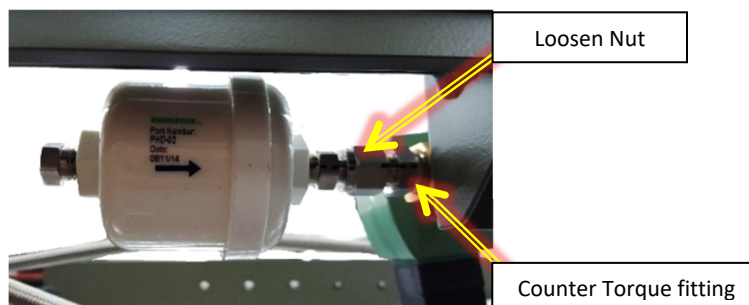
4.3.4 Replacing the SWS Cartridge

1. Remove inlet and outlet hoses from the blue housing.
2. For S/N's AFS-0001 through AFS-0255, remove the bungee cords and slide the blue housing out from the SWS frame. For S/N's after AFS-0255, remove the bracket that secures the blue housing by loosening the two panel fasteners and slide the blue housing out from the SWS frame.
3. Use the supplied spanner wrench stored inside the SWS frame to remove the blue housing from the black top.
4. Slide the old cartridge out and discard.
5. Slide the new cartridge in place, ensuring the gasketed side is up towards the opening of the housing.
6. Verify large Blue Housing O-ring is in place and is lubricated with silicone grease.
7. Follow steps 1-3 in reverse order to return the SWS to operation.



4.3.5 Replacing the HEPA Filter

1. Turn OFF the SMU, disconnect power, and ensure pressure in the chamber and jacket is at 0 psig.
2. Remove the left side panel of the SMU.
3. Using an 11/16" wrench to counter-torque the fitting near solenoid valve, use an 11/16" wrench to loosen the fitting nut at the filter.
4. Install the new HEPA filter by following steps 1-3 in reverse order.



4.3.6 Replacing the Steam Trap

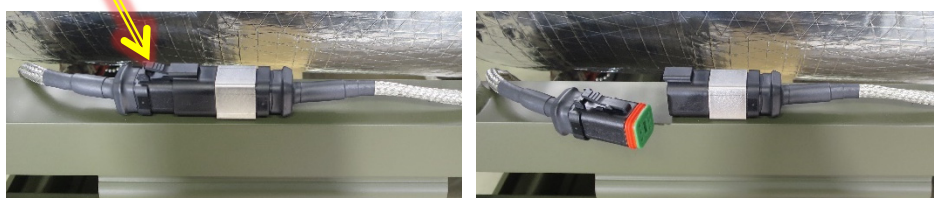
1. Turn off the SMU, disconnect power, and ensure pressure in the chamber and jacket is at 0 psig.
2. Disconnect all three hoses from the WRS.

3. Disconnect the electrical plug to the WRS.
4. Pull the WRS out from underneath the SMU and remove the left side panel.
5. Disconnect the top of the steam trap by using a 7/8" wrench to loosen the fitting nut at the bulkhead.
6. Disconnect the bottom of the steam trap by using a 13/16" wrench to counter-torque the fitting on the steam trap while using a 7/8" wrench to loosen the hose connection fitting.
NOTE: On S/N's after AFS-0236, loosen the nut attached to the 90° fitting.
7. Remove the port connector from the 45° fitting and reinstall it on the new steam trap.
8. Install the new steam trap by following steps 1-6 in reverse order.
NOTE: On S/N's after AFS-0236, install the supplied port connector on the steam trap outlet.

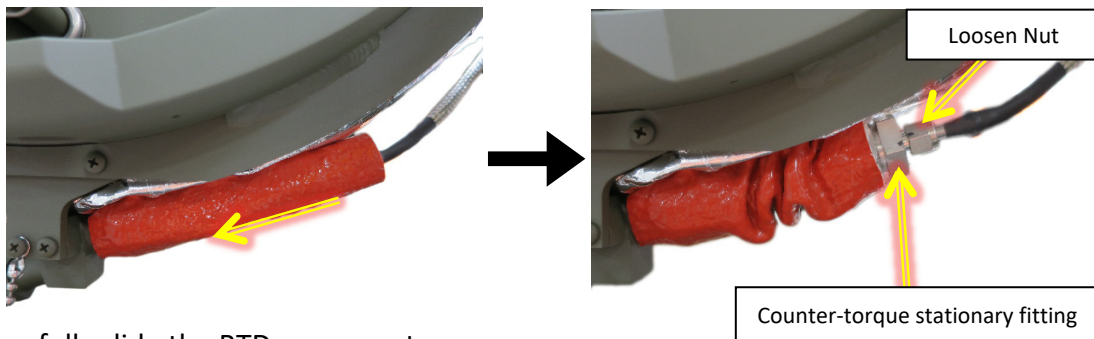
4.3.7 Replacing the RTD Sensor

1. Turn OFF the SMU, disconnect power, and ensure pressure in the chamber and jacket is at 0 psig.
2. Remove the front bottom panel on the SMU.
3. Remove the right side panel on the SMU.
4. Disconnect the RTD Connector. This connector is located on the frame cross-bar.

Press down the clip and then slide out the connector. Pull on the connector, not the wiring.



5. Carefully slide the insulation sleeve down away from the RTD wiring.
6. Use a 13/16" wrench to counter-torque the fitting while using a 9/16" wrench to loosen the 1/4" fitting nut (located at the top/right).



7. Carefully slide the RTD sensor out.
8. Install the new RTD Sensor by following steps 1-7 in reverse order.

4.3.8 Replacing the Chamber Door Gasket

NOTE: The chamber door gasket should be replaced whenever a leak is detected around the door. Contact FDI for authorized replacement parts (Reference Section 4.4 – Recommended Replacement Parts).

1. Turn OFF the SMU, disconnect power, and ensure pressure in the chamber and jacket is at 0 psig.
2. Open chamber door and carefully remove the old door gasket. Be sure not to nick or cut the gasket or scratch the groove in the aluminum door.
3. Inspect the gasket groove to ensure that it is clean and smooth.
4. Install a new gasket (Reference Section 4.4 – Recommended Replacement Parts) by aligning the gasket with the door groove and pushing it into place with your fingers at four equidistant locations around the groove (e.g., 12, 3, 6, and 9 o'clock). Soap and water will ease the installation. Carefully work the gasket into the groove until it is evenly distributed around the door. Working from one point only will result in too much or too little gasket left over at the other side of the door. Wipe the gasket and the mating face on the chamber door frame to ensure that no debris could cause a leak path.

4.3.9 Replacing the Chamber Doorpost O-Ring

NOTE: The O-ring under the doorpost should be replaced whenever a leak is detected at the doorpost or when the doorpost is refitted. Contact FDI for replacement parts (Reference Section 4.4 - Recommended Replacement Parts).

1. Turn OFF the SMU, disconnect power, and ensure pressure in the chamber and jacket is at 0 psig.
2. Open the chamber door and remove the handwheel retainer (large washer) on the outboard end of the doorpost.
3. Remove the six radial arm wire retainers.
4. Rotate the handwheel assembly until the entire assembly unscrews from the doorpost.
5. Remove the three doorpost screws on the inside of the door and carefully tap out the doorpost using a soft mallet.
6. Remove the old doorpost O-ring and clean the O-ring groove on the door and the O-ring seating area on the doorpost.
7. Lightly lubricate the new doorpost O-ring with grease and install on the doorpost.
8. Insert the doorpost into the door and insert the three bolts. Lightly tighten the doorpost against the door.
9. Clean and re-grease the doorpost threads with a high-temperature (275°F) NLGI #2 grease.
10. Ensuring that the hole in the hub flange lines up with the peg in the door, install and screw on the handwheel assembly. Reinstall the six radial arm wire retainers.
11. Firmly tighten the handwheel assembly against the door to draw the back of the doorpost against the door.
12. Tighten the three bolts on the back of the door to 90-inch-lb of torque.

WARNING: The threads in the door are aluminum. Do not over-torque.

4.3.10 Replacing the Electric Immersion Heating Elements

NOTE: With wires disconnected, the resistance of the heaters should be between 16.7 and 19.4 Ohms.

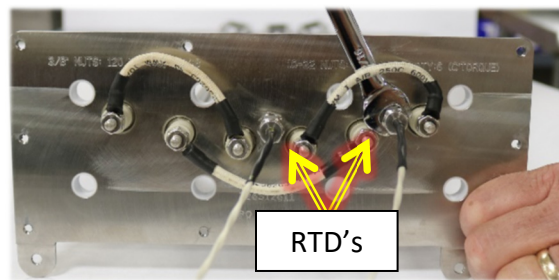
1. Turn OFF the SMU, disconnect power, and ensure pressure in the chamber and jacket is at 0 psig.
2. Remove Back Lower Panel, Heater Assembly Cover, and Heater Block Enclosure. Then disconnect the 3 incoming heater wires, noting the exact connections of each wire. Disconnect the white RTD Connector. (Reference Section 4.3.17 - Removing Back Lower Panel and Heater Assembly Cover)



3. Remove the 8 white heater stud caps (S/N's after AFS-0340), nuts, and washers from the studs and pull the heater plate from the jacket. The gasket should be removed and discarded.



4. If the middle heater is being replaced, remove the RTD's and set aside to protect them. Transfer the springs to the new heater element by unwinding/winding them on the element.



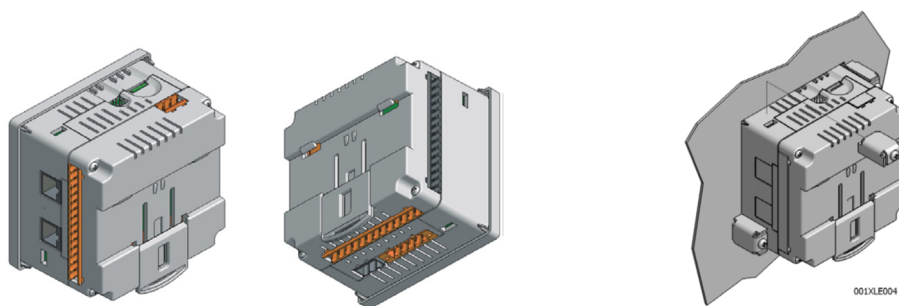
5. Loosen the 2 nuts on the compression fitting for the heater to be replaced. Slide the heating element from the plate and discard the element, nut, and ferrule (which should still be crimped to the element).
6. Remove the heater support that is clipped onto the end of the heating element (this clip supports the end of the heating element and prevents it from resting on the surface of the jacket).
7. Install the heater support onto the end of the replacement heating element. Ensure Teflon screw is installed snugly into the heater support.

8. Slide new compression fitting nuts and then ferrules over the ends of the replacement heaters.
9. Insert the ends of the heating elements into the male fittings in the heater plate. Ensure that the ends of the heaters do not protrude too far, which would potentially interfere with the cover of the heater box. Insert a wrench or other flat tool through the loop end of the heating element to prevent it from twisting. Tighten the compression fitting nut firmly using an 11/16" flare nut wrench.
10. Reinstall RTD's by inserting into Swagelok fitting and tightening nut finger tight then 1/4 turn. The long RTD is installed in the right fitting, on right leg of center heater element. The short RTD is installed in the center fitting, on left leg of center heater element.
11. On the long probe, compress and slide a spring to the center of the probe. On both the long and short probe, compress and slide the spring over the end of the RTD's until approximately 3/8" of the RTD probe extends beyond the spring.
12. Slide a new heater block gasket over the stud bolts on the heater block.
13. Insert the heater assembly into the jacket opening and over the stud bolts. Ensure the white Teflon isolation bushings are reused and are flush.
14. Place isolation washers (up against heater plate), large stainless washers, lock washers and nuts onto the stud bolts, and tighten using a circular-type pattern to slowly and evenly compress the gasket to make a water-tight seal. Using a torque wrench, tighten each nut to a final torque of 120 inch-lb.
15. Making sure to counter-torque on the inner nut with 3/8" wrench and a torque wrench on the outer nut, reconnect all the heater wires and tighten to a final torque of 35 inch-lb.
16. Reconnect the white RTD Connector.
17. Reinstall the Heater Plate Enclosure, Gasket (notch side down), Heater Assembly Cover, and Back Lower Panel.
18. Inspect heater block for leaks upon first use.

4.3.11 Replacing the PLC

NOTE: Please reference the Horner XLT103 manual found on the CD for further information.

CAUTION: Be aware that the glass fiber optic cable for the door switch is located near the back of the PLC. Use caution when removing the PLC so that the fiber optic cable does not get damaged.



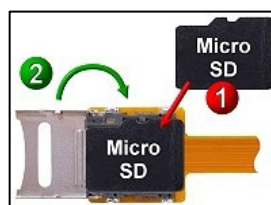
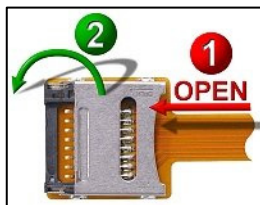
1. Turn SMU to OFF and then back ON. Record the software version as it flashes on the screen for approximately 2 seconds.
2. Record the number of CYCLES from the "STATUS" screen.
3. Ensure power to unit is OFF and the incoming power is disconnected.
4. Remove the right-side panel for access to the electrical box.
5. Gently remove the MJ2 connector (RJ45 connector near side).
6. Gently remove the orange J1 connector (near side) and the black J2 connector (far side).
7. Gently remove the incoming power connector (bottom side).
8. While holding the PLC from the front of the sterilizer to keep it from falling out, remove the 4 gold-colored mounting clips from the slots in the PLC case.
9. Pull the PLC out through the front of the sterilizer.
10. Document the serial numbers of the old and the new PLCs in the maintenance log.
11. Make sure the gasket is installed on the PLC and is free from dust and debris. Check that the corners of the gasket are secure.
12. Insert the new PLC into the panel.
13. Insert the 4 mounting clips into the slots in the PLC case. One clip should be installed on each corner.
14. Lightly tighten each screw so the clip is held in place.
15. Tighten the screws on the clips such that the gasket is compressed against the panel.
16. Reinstall the incoming power connector (bottom side).
17. Reinstall the black J2 connector (far side) and the orange J1 connector (near side).
18. Reinstall the MJ2 connector (RJ45 connector near side).
19. Connect the incoming power to the sterilizer.
20. Turn the sterilizer ON.
21. As the PLC boots up, take note of the software version as it flashes on the screen for approximately 2 seconds. If the software version in the newly installed PLC is older than what was noted in Step 1, the software should be updated. Contact FDI for update information and procedures.
22. Reset settings using the "CONFIRM SETUP" screen, including resetting the barometric pressure.
23. Update the number of CYCLES from the "STATUS" screen by pressing on the number itself and entering the correct number of cycles from the previous PLC. This will maintain the running history of the number of cycles performed by this sterilizer.
24. Perform biological and performance testing per AAMI ST79 on the sterilizer to qualify the efficacy and performance.

4.3.12 PLC Software Update

The following is the procedure for updating the software in the P2131 Automated Field Steam Sterilizer using the Micro SD card that is shipped with each sterilizer.

NOTE: This procedure should only be performed by a qualified Maintenance Technician

1. The updated software file will be delivered via email.
2. Using the Micro SD card and adapter supplied with each sterilizer, save the file onto the Micro SD card with your computer.
3. Ensure the sterilizer is OFF.
4. Insert the Micro SD card (without the adapter) into the extender cable and insert the other end of the cable into the top of the Programmable Logic Controller (PLC). The exposed pins should face toward the front of the sterilizer.



5. Note the firmware version number by turning the sterilizer ON and watching the first screen that appears. The firmware version number will display for only 2 seconds.
6. From the CONFIRM SETUP screen, press the F4 function key. (F4 is only accessible from this screen.)
7. The UPDATE SOFTWARE screen will display and the PLC will initialize the Micro SD card. This may take a few minutes after which a list of files will appear.
8. Use the up and down arrow keys on the right-hand side of the screen to select the new software file. (Example: V1285 OR V1043)
9. Choose OK when you are asked if you are sure you want to load the application.
10. A moving clock and progress bars will appear while the software is loaded. This may take a few minutes.
11. Next, you will see LOAD PAGE COMPLETE and you will be asked if you would like to place the PLC in RUN mode. Choose OK. (Choosing CANCEL will place the PLC in IDLE mode and the software will not operate.)
12. The software will restart and the CONFIRM SETUP screen will appear.
13. Turn the sterilizer OFF and remove the Micro SD card and extender cable.
14. The new software is now installed and the sterilizer is ready to operate.

4.3.13 PLC Firmware Update

The following is the procedure for updating the firmware in the P2131 Automated Field Steam Sterilizer using the P2131 FIRMWARE UPDATE KIT from Fort Defiance Industries.

NOTE: This procedure should only be performed by a qualified Maintenance Technician

The P2131 FIRMWARE UPDATE KIT includes the following items:

- CD with Cscape programming software
- CD with the new PLC firmware
- Micro SD card and adapter with the sterilizer software program
- Micro SD extender cable
- Communication cable
- Instruction sheet

WARNING: Firmware updates typically delete the user applications to ensure compatibility. After updating the firmware, you will need to reload the sterilizer software program. **Make sure the sterilizer software program is available before beginning the firmware update.**

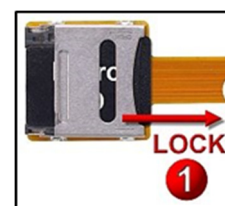
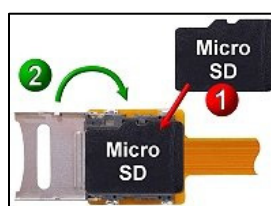
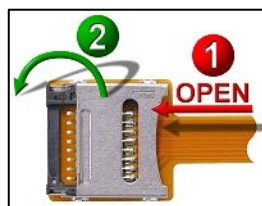
Step 1 – Loading the New Firmware

1. Insert the CD with Cscape software and install the Cscape programming software to your computer. **NOTE:** Computer must be a PC with Windows 7 or newer operating system.
2. Insert the CD with the new PLC firmware, and run the XLe-XLt-firmware application from the CD. This will save several files into the Cscape/Firmware folder on your computer. Verify that these files are in the correct folder on your computer.
3. Ensure the sterilizer is OFF, and connect the communication cable to a serial COM port on your computer and to MJ1 on the Programmable Logic Controller (PLC).
4. Turn the sterilizer ON.
5. Open Cscape on your computer and establish communication between Cscape and the PLC.
 - a. At the ABOUT Cscape window, choose OK.
 - b. On the CONNECTION WIZARD window, select SERIAL and choose NEXT.
 - c. On the following window, enter the COM port number that you are using for communication and choose FINISH.
6. Within Cscape select FILE and then NEW to create a new blank program. This blank program is only used to access the firmware update wizard.
7. Start the firmware update by selecting FILE and then FIRMWARE UPDATE WIZARD.
8. In the Firmware Update Wizard, select XLT for the Product Type and CsCAN NETWORK for Networking and choose OK.
9. On the following window choose OK to accept FIRMWARE UPDATES USE HIGH SPEED SERIAL COMMUNICATIONS.
10. The PLC will enter the System Firmware Loader mode and the FIRMWARE UPDATE window will appear. Choose START to begin the update. CAUTION - Once the download starts, do not interrupt the communication link while the download is in progress. Doing so will permanently lock the PLC.
11. Wait for the firmware update to complete. You will see a progress bar as the firmware is being updated.
12. When you see DOWNLOAD COMPLETE, choose CLOSE.
13. At the UPDATE COMPLETE window, choose OK.

14. To double-check the download, in Cscape choose CONTROLLER then STATUS. This will show the latest firmware revision on the PLC. This should match what was downloaded. The Self-Test may fail because there is not a program in the PLC. Choose CLOSE to exit the window.
15. After the firmware update, the PLC is in IDLE mode. To switch it to RUN mode in Cscape choose CONTROLLER and then RUN/MONITOR.
16. Turn the sterilizer OFF.

Step 2 – Reloading the Sterilizer Software Program

1. Insert the Micro SD card (without the adapter) into the extender cable and insert the other end of the cable into the top of the Programmable Logic Controller (PLC). The exposed pins should face toward the front of the sterilizer.



2. Turn the sterilizer ON and watch the first screen that appears and note the firmware version number that appears. **NOTE:** The firmware version number will display for only 2 seconds.
3. Press the SYSTEM button.
4. From the SYSTEM MENU use the up and down arrow keys on the right-hand side of the screen to select REMOVABLE MEDIA. Press the RETURN button.
5. The Media Directory screen will display and the PLC will initialize the Micro SD card. This may take a few minutes after which a list of files will appear.
6. Use the up and down arrow keys on the right-hand side of the screen to select the software file that matches the firmware version number. (For example, if the firmware version is 12.85, then choose software file 1285.pgm). Press RETURN.
7. Choose OK when you are asked if you are sure you want to load the application.
8. A moving clock and progress bars will appear while the software is loaded. This may take a few minutes.
9. If the incorrect software was chosen, you will see MEDIA ERROR – INCOMPATIBLE VERSION. If this happens then choose OK and select the correct program. Choose OK when you are asked if you are sure you want to load the application.
10. If the correct software was selected, you will see LOAD PAGE COMPLETE and you will be asked if you would like to place the PLC in RUN mode. Choose OK. (Choosing CANCEL will place the PLC in IDLE mode and the software will not operate.)
11. The software will restart and the CONFIRM SETUP screen will appear.
12. Turn the sterilizer OFF and remove the Micro SD card and extender cable.
13. The new software is now installed and the sterilizer is ready to operate.
14. Test the operation of the sterilizer with the new firmware before returning the sterilizer to service.

4.3.14 Vacuum Leak Test Troubleshooting Guide

Air leaks into the sterilizer can be problematic since the purpose of a dynamic air removal sterilizer (i.e., pre-vacuum sterilizer) is to remove the air to enable more effective sterilization. Vacuum leaks are often difficult to diagnose since a small vacuum leak might not be visible with steam under pressure. If the P2131 sterilizer fails a Vacuum Leak Test, the following Vacuum Leak Troubleshooting Guide should be used by a qualified maintenance technician to help find the root cause of the vacuum leak.

The source of the vacuum is the water eductor that is located inside the WRS. Water flowing through an internal tapered nozzle uses the Venturi effect to create a drop in pressure at the tip of the nozzle. This pressure drop creates the source of vacuum for the SMU chamber. The green highlighted areas of the Process Flow Diagram in Section 4.6 show the parts of the system that experience vacuum during the conditioning phase (pre-vacuum pulses) and the drying phase. Using this diagram in conjunction with the Vacuum Leak Troubleshooting Guide should help the maintenance technician diagnose and correct the source of the vacuum leak.

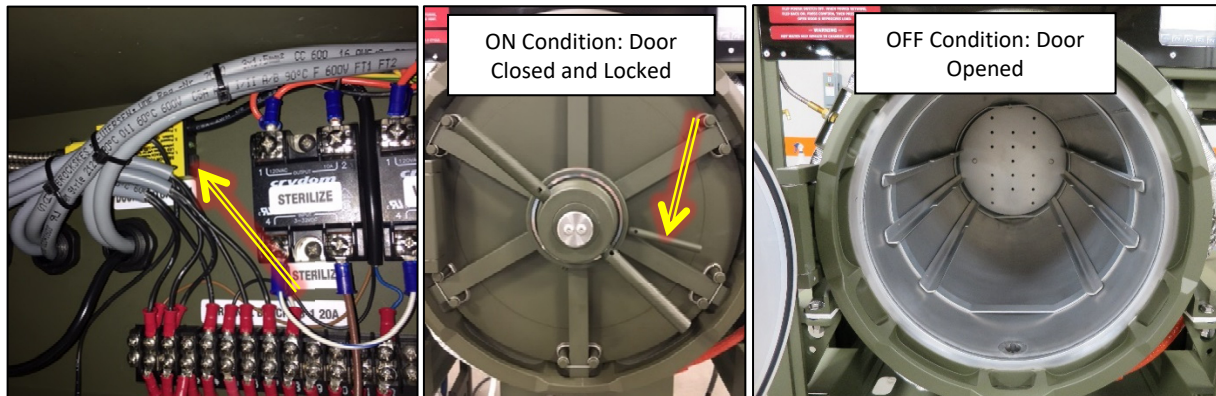
Please see the full troubleshooting guide in Appendix A.5 – Vacuum Leak Test Troubleshooting Guide.

4.3.15 Door Switch Reprogramming

The door switch may cease to operate correctly if, (1) maintenance on the door is performed, (2) the door becomes misaligned, or (3) the door switch is replaced. To check for correct door switch operation, navigate to the STATUS screen and note that the indication is either DOOR OPENED or DOOR CLOSED depending on the position of the Door Locking Arm Lever.

WARNING: This must be performed with the sterilizer turned ON. Be cautious of high voltage within the electrical enclosure.

1. To reprogram the door switch, remove the right side panel to expose the electrical enclosure. Locate the yellow door switch in the upper left portion of the enclosure.
2. Press the black TEACH button on the side of the door switch sensor until the green LED turns to yellow or blinks red.
3. Present the ON condition, which is the door closed and the Locking Arm Lever rotated clockwise until the radial arms are fully extended. Press the TEACH button and the yellow LED will turn off.
4. Present the OFF condition, which is the door in the fully open position. Press the TEACH button and the LED will turn green, confirming the new settings have been accepted.
5. Test for correct operation by observing the STATUS screen while operating the door.

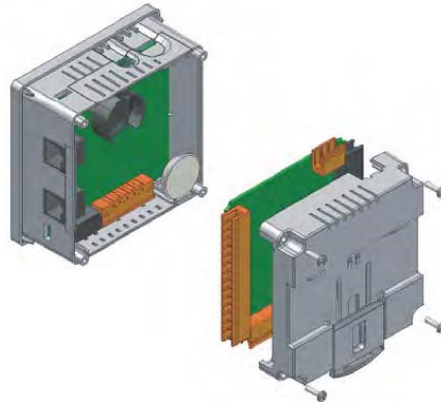


4.3.16 Replacing the PLC Battery

WARNING: Lithium batteries may explode or catch fire if damaged. Do not recharge, disassemble, heat above 100°C (212°F), incinerate, or puncture.

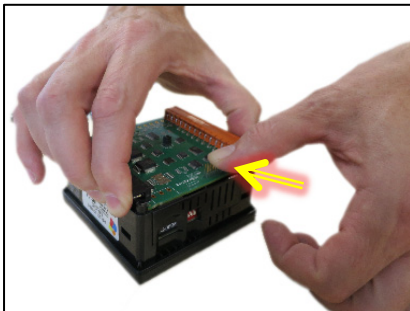
NOTE: Disposal of lithium batteries must be done in accordance with federal, state, and local regulations. Be sure to consult with the appropriate regulatory agencies before disposing batteries.

NOTE: Do not make substitutions for the battery. The Horner XLt PLC uses a coin lithium battery (P/N: P2131-1-9002).

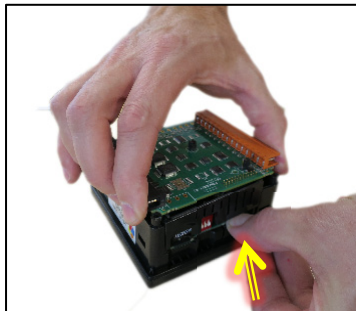


1. Replacing the Battery

- a. Record the CYCLE COUNT from the STATUS screen for use later.
- b. Disconnect all power from sterilizer.
- c. Remove the PLC from the sterilizer (see Section 4.3.11).
- d. Remove the 4 screws on the back of the PLC and remove the back cover.
- e. Remove the I/O board by carefully lifting it straight up:



Press on pins with thumb, while pulling on edges of the I/O board



Once loosened, hold down edge of bottom PC board while pulling up on I/O board

- f. Remove the old battery. It may require a small flat blade screwdriver to lift it from the holder. Be careful not to permanently deform the battery holder tab.
- g. Dispose of the battery properly per the above note on disposal regulations.
- h. Slide the new battery into the holder. Make sure the battery is inserted with the proper polarity. The top tab of the battery holder should contact the positive (+) terminal of the battery.
- i. Place the I/O board back into the case by aligning the connector and carefully pressing straight down.
- j. Place the back cover back on the unit and tighten all four (4) screws.

2. Reinstalling the PLC

- a. Install the Micro SD card into the MEMORY slot on top of the PLC with the contacts of the card toward the front of the PLC. It should spring into place. (After this Battery Replacement Procedure is completely finished, the card can be left in the PLC indefinitely or returned to the plastic case in the Sterilizer Accessory Bag.)
- b. Reinstall the PLC into the sterilizer (see Section 4.3.11).
- c. Verify that the MODBUS cable is installed in the MJ2 port on the PLC.
- d. Apply power to the unit.
- e. As the unit powers up, you should see several error screens and finally a screen that says, “No User Screens to Display”.

3. Updating the “Screen Update Time”

- a. Press the SYSTEM button.
- b. Arrow down to SET SCREEN and choose ENTER (↵).
- c. Arrow down to UPDATE TIME (mS) and choose ENTER (↵).
- d. Change the time to 47 and choose ENTER (↵).
- e. Choose ESC.

4. Loading the Program

- a. Arrow down to REMOVABLE MEDIA and choose ENTER (↵).
- b. Arrow down to the program (examples – 1285.PGM, V1043.PGM) and choose ENTER (↵).
- c. Choose OK and wait for the program to load.
- d. When you see “PLACE IN RUN MODE?” choose OK.

5. Updating data after program boots up

- a. From the CONFIRM screen
 - i. Time
 - ii. Date
 - iii. Unit ID
 - iv. Barometric Pressure
- b. From the STATUS screen
 - i. Cycle Count (press the number to update).

6. Record the battery replacement in your maintenance log with the cycle count.

4.3.17 Removing Back Lower Panel and Heater Assembly Cover

CAUTION: This procedure must be performed with the sterilizer OFF and cooled to room temperature. Be cautious of pinch points.

1. Removing/Installing the Back Lower Panel

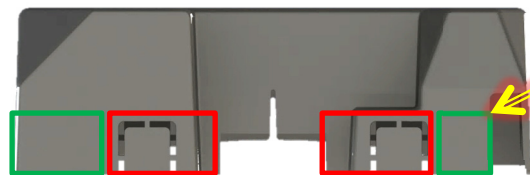
- Use a Multi-tool to unfasten the latches (3x) and carefully remove the Back Lower Panel.



- Follow Step 1a in reverse order to install the Back Lower Panel

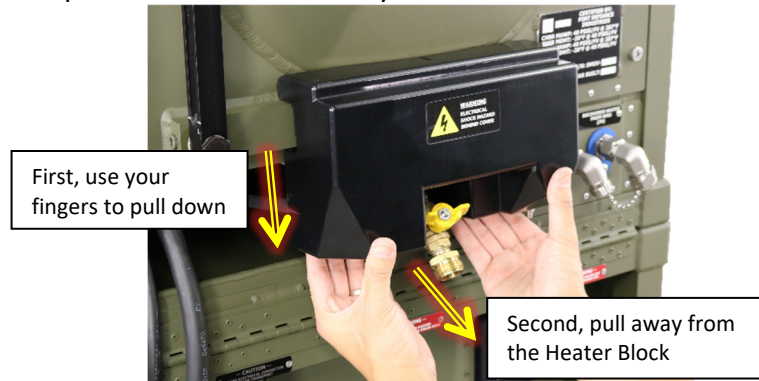
2. Removing the Heater Assembly Cover

- Carefully position your hands to grab underneath the black Heater Assembly Cover.



Bottom View
Green – Recommended areas to grab and pull
Red – Not recommended areas to grab and pull

- First pull down and then away from the Heater Block Enclosure.



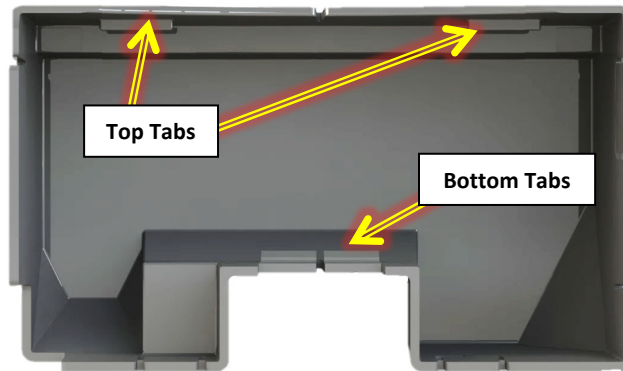
Second, pull away from the Heater Block

- Carefully remove the Heater Assembly Cover.



3. Installing the Heater Assembly Cover

Note: There are two tabs located on the Top and Bottom within the Cover.



- a. Position Top Tabs over the top flange of the Heater Block Enclosure as shown.



- b. Slowly lower the Heater Assembly Cover over the Heater Block Enclosure.
Note: The two bottom tabs are designed to secure the black Heater Cover to the bottom flange of the Heater Block Enclosure.
- c. Tap the center of black Heater Assembly Cover with a Dead Blow Hammer or the bottom of the fist until it clips into place.



- d. Check the fit of the black Heater Assembly Cover. It is designed for a close fit and should not be able to be removed easily.

4.4 Replacement Parts

WARNING: Replacement parts should be sourced from FDI. Use of unauthorized parts could be of inferior quality, configuration, or specification and could compromise the safety and/or efficacy of the sterilizer and will void the warranty.

NOTE: Nomenclature within parentheses is for reference on the Process Flow Diagram and Electrical Wiring Diagrams, sections 4.6 and 4.7 respectively.

*Parts with an * are FDI recommended spare parts to stock.*

SMU Replacement Parts

Item	Description	Part Number
1.	ALARM, BUZZER (ALM-1)	P2131-1-4008
2.	BATTERY, HORNER PLC (PKG OF 4)	P2131-1-9002
3.	BLOCK, FUSE, INCOMING POWER (FB1)	P2131-1-4023
4.	BLOCK, FUSE, SMALLER FUSES, 6 POSITION (FB2)	P2131-1-4025
5.	BLOCK, TERMINAL, 12 POSITION (TB1)	P2131-1-4022
6.	BLOCK, TERMINAL, 30A (TB2)	P2131-1-4026
7.	CONNECTION, JACKET DRAIN HOSE	P2131-1-9009
8.	CONNECTION, RECOVERED WATER HOSE (BLUE-TAGGED)	P2131-1-9007
9.	CONNECTION, VACUUM/EXHAUSE HOSE (WHITE-TAGGED)	P2131-1-9007
10.	CONNECTOR, DUAL RTD WIRING	P2131-1-4021
11.	CONTACTOR, MAIN POWER FOR HEATER ELEMENTS (C1)	P2131-1-4002
12.	CONTROLLER, PROGRAMMABLE LOGIC	P2131-1-4000*
13.	COVER, HEATER ASSEMBLY	P2131-1-9040
14.	ELEMENT, ELECTRIC HEATING (H1, H2, H3)	P2131-1-4001
15.	FAN, ELECTRICAL BOX COOLING (F1)	P2131-1-4011
16.	FILTER, ELECTRICAL BOX AIR INLET	P2131-1-5001
17.	FILTER, HEPA	P2131-1-0028*
18.	FUSE, 30A, TIME DELAY (FB1-A THROUGH FB1-C) (PKG OF 3)	P2131-1-4012*
19.	FUSE, 750mA, SLOW BLOW (FB2-1 THROUGH FB2-6) (PKG OF 6)	P2131-1-4013*
20.	GASKET, CHAMBER DOOR POST (FLAT, WHITE)	P2131-1-1143
21.	GASKET, HEATER ENCLOSURE	P2131-1-1114
22.	GASKET, HEATER FLANGE	P2131-1-1032
23.	GASKET, JACKET DRAIN/FILL	P2131-1-1173
24.	GASKET, LIQUID LEVEL SWITCH	P2131-1-1170
25.	GAUGE, ANALOG, CHAMBER ASSEMBLY (S/N'S AFS-0001 THROUGH 0236)	P2131-1-9026
26.	GAUGE, ANALOG, CHAMBER ASSEMBLY (S/N'S AFTER AFS-0236)	P2131-1-9028
27.	GAUGE, ANALOG, JACKET ASSEMBLY (ALL S/N'S)	P2131-1-9025

Item	Description	Part Number
28.	GAUGE, ANALOG, UPGRADE KIT (S/N'S AFS-0001 THROUGH 0236)	P2131-1-9027
29.	GAUGE, LEVEL SIGHT	P2131-1-3405
30.	HANDLE, CHAMBER DOOR	P2131-1-1020
31.	HEATER STUD CAP	P2131-1-1168
32.	HOSE, CONDENSATE (RED-TAGGED)	P2131-1-3103
33.	HOSE, HIGH TEMPERATURE DRAIN	P2131-1-3104
34.	HOSE, RECOVERED WATER (BLUE-TAGGED)	P2131-1-3101
35.	HOSE, VACUUM/EXHAUST (WHITE-TAGGED)	P2131-1-3102
36.	KIT, SOLENOID VALVE REPAIR (SV-1, SV-2, SV-3, SV-4, SV-5)	P2131-1-9001*
37.	KNOB, ENDCAP	P2131-1-0020
38.	LEVER, LOCKING ARM	P2131-1-1023
39.	LIGHT, INDICATOR, LED (LAMP-1)	P2131-1-4018
40.	MANIFOLD, CHAMBER DRAIN	P2131-1-0022
41.	MANUAL, P2131 TECHNICAL, WITH CD	P2131-1-8001
42.	MODULE, RTD (RTD-1, RTD-2) TRANSMITTER	P2131-1-4006
43.	MULTI-TOOL	P2131-1-2020
44.	O-RING, CHAMBER DOOR GASKET (PKG OF 2)	P2131-1-1029*
45.	O-RING, CHAMBER DOOR POST (PKG OF 5)	P2131-1-1121*
46.	O-RING, CHAMBER DRAIN SCREEN	P2131-1-1150
47.	O-RING, LEVEL SIGHT GAUGE (PKG OF 50)	P2131-1-9019
48.	O-RING, SMU TO WRS HOSES (WHITE/TAGGED HOSES) (PKG OF 25)	P2131-1-3408*
49.	OUTLET, CHAMBER VENT VALVE	P2131-1-9008
50.	OUTLET, JACKET VENT VALVE	P2131-1-9008
51.	POWER SUPPLY, DC (PS-1)	P2131-1-4003
52.	RECEPTACLE, MAIN POWER CORD-CONNECTING	P2131-1-4027
53.	RELAY, SOLID STATE, FOR HEATERS (SSR-6, SSR-7, SSR-8)	P2131-1-4004*
54.	RELAY, SOLID STATE, FOR VALVES & WRS (SSR-1 THROUGH SSR-5)	P2131-1-4005*
55.	SCREEN, CHAMBER DRAIN	P2131-1-0019
56.	SD CARD EXTENDER FOR PLC	P2131-1-4028
57.	SD CARD, WITH ADAPTER	P2131-1-4020
58.	SENSOR, DUAL RTD (RTD-1 & RTD-2)	P2131-1-0023*
59.	SENSORS, HTS-1 RTD (RTD-3 & RTD-4)	P2131-1-0049*
60.	SHELF, CHAMBER RACK, LOWER	P2131-1-2003
61.	SHELF, CHAMBER RACK, UPPER	P2131-1-2002
62.	SHIM, LEVELING, (SET OF 12)	P2131-1-2016
63.	STRIP, TERMINAL, FOR INCOMING NEUTRAL WIRE (2 POSITION) (TB-3)	P2131-1-4024
64.	SWITCH, CHAMBER DOOR, FIBER OPTIC (DS-1)	P2131-1-4009
65.	SWITCH, HIGH TEMPERATURE LIMIT (HTS-1)	P2131-1-4033
66.	SWITCH, JACKET WATER LEVEL (FS-1)	P2131-1-4016

Item	Description	Part Number
67.	SWITCH, MAIN POWER (SW-1)	P2131-1-4017
68.	TRANSMITTER, CHAMBER PRESSURE (PT-2)	P2131-1-4014
69.	TRANSMITTER, JACKET PRESSURE (PT-1)	P2131-1-4014
70.	VALVE, CHAMBER VENT	P2131-1-0034
71.	VALVE, CHECK, RECOVERED WATER	P2131-1-3402
72.	VALVE, JACKET DRAIN	P2131-1-0039
73.	VALVE, JACKET PRESSURE SAFETY	P2131-1-3403
74.	VALVE, JACKET VENT	P2131-1-0035
75.	VALVE, SOLENOID, STERILIZE (SV-1)	P2131-1-0024
76.	VALVE, SOLENOID, VACUUM BREAK (SV-3)	P2131-1-0026
77.	VALVE, SOLENOID, VACUUM BREAK (SV-4)	P2131-1-0027
78.	VALVE, SOLENOID, VACUUM/EXHAUST (SV-2)	P2131-1-0025

WRS Replacement Parts

Item	Description	Part Number
79.	CONNECTION, PUMP DRAIN	P2131-2-0047
80.	CONNECTION, TANK DRAIN	P2131-2-0045
81.	CONNECTION, WATER FILL	P2131-2-0046
82.	CONNECTION, CONDENSATE (RED-TAGGED)	P2131-2-0009
83.	CONNECTION, RECOVERED WATER (BLUE-TAGGED)	P2131-2-0009
84.	CONNECTION, VACUUM/EXHAUST (WHITE-TAGGED)	P2131-2-0009
85.	COOLER, HEAT EXCHANGER (S/N'S AFS-0001 THROUGH 0236)	P2131-2-3000
86.	COOLER, HEAT EXCHANGER (S/N'S AFTER AFS-0333)	P2131-2-9009
87.	COOLER, HEAT EXCHANGER, UPGRADE KIT (S/N'S AFS-0237 THROUGH AFS-0333)	P2131-2-9010
88.	EDUCTOR, VACUUM	P2131-2-3402
89.	FAN, WRS HEAT EXCHANGER (F2)	P2131-2-4004
90.	KIT, SOLENOID VALVE REPAIR (SV-6)	P2131-2-9001*
91.	MOTOR, ELECTRIC (M)	P2131-2-4001
92.	PLUG, BLEACH FILL PORT & BREATHER (S/N'S AFTER AFS-0236)	P2131-2-3019
93.	PLUG, BLEACH FILL PORT (S/N'S AFS-0001 THROUGH 0236)	P2131-2-9003
94.	PLUG, WRS POWER	P2131-2-4010
95.	PUMP, WATER (INCLUDING MOTOR) (S/N'S AFTER AFS-0236)	P2131-2-9008
96.	PUMP, WATER (S/N'S AFS-0001 THROUGH 0236)	P2131-2-3403
97.	RECEPTACLE, WRS POWER CORD	P2131-2-0014
98.	RELAY, K1, K2, AND K3	P2131-2-4006
99.	RELAY, K4	P2131-2-4007
100.	SEAL, WRS PUMP	P2131-2-9002*

Item	Description	Part Number
101.	SWITCH, LIQUID LEVEL (LS-1)	P2131-2-4003
102.	SWITCH, ROCKER, WATER RETURN (SW-2)	P2131-2-4009
103.	SWITCH, WRS POWER (SW-3)	P2131-2-4008
104.	TANK, STAINLESS, WATER (S/N'S AFTER AFS-0236)	P2131-2-9007
105.	TANK, WATER	P2131-2-0008
106.	TRAP, STEAM	P2131-2-3401*
107.	VALVE, CHECK, EDUCTOR	P2131-1-3402
108.	VALVE, CHECK, FILL (S/N'S AFS-0001 THROUGH 0236)	P2131-2-3407
109.	VALVE, CHECK, PRESSURE (S/N'S AFS-0001 THROUGH 0236)	P2131-2-3406
110.	VALVE, CHECK, STEAM TRAP	P2131-1-3402
111.	VALVE, CHECK, TANK DRAIN (S/N'S AFS-0001 THROUGH 0236)	P2131-2-3405
112.	VALVE, CHECK, VACUUM (S/N'S AFS-0001 THROUGH 0236)	P2131-2-3406
113.	VALVE, PRESSURE SAFETY RELIEF	P2131-2-3404
114.	VALVE, SOLENOID, WRS CIRCULATION (SV-6)	P2131-2-0005
115.	VALVE, SOLENOID, WRS FILL (SV-5)	P2131-2-0004
116.	VALVE, TANK PRESSURE RELIEF (S/N'S AFTER AFS-0236)	P2131-2-9010

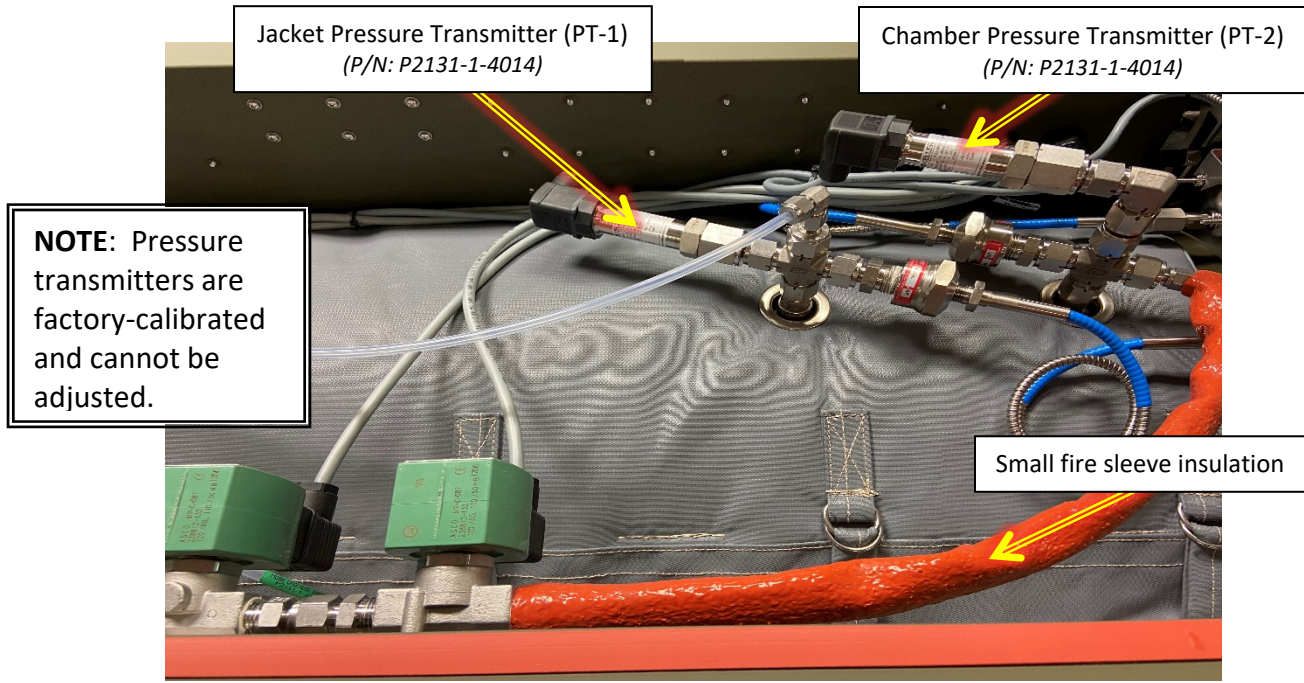
SWS Replacement Parts

Item	Description	Part Number
117.	CARTRIDGE, DEIONIZED WATER (PACK OF 6)	P2131-3-9008
118.	CONNECTION, INLET HOSE	P2131-3-3004
119.	CONNECTION, OUTLET HOSE	P2131-3-3005
120.	GASKET, CAM AND GROOVE FITTING (PKG OF 10)	P2131-3-9004
121.	GASKET, GARDEN HOSE FITTING (PKG OF 10)	P2131-3-9005
122.	HOSE, MANUAL PUMP DISCHARGE	P2131-3-3008
123.	HOSE, OUTLET	P2131-3-3006
124.	HOSE, SUCTION LINE TO MANUAL PUMP	P2131-3-3007
125.	HOUSING, PENTEK BIG BLUE, 20" X 3/4"	P2131-3-9013
126.	METER, HANDHELD TOTAL DISSOLVED SOLIDS (TDS)	P2131-3-9010
127.	O-RING, DI HOUSING, W/ SILICONE GREASE	P2131-3-9011
128.	O-RING, MANUAL PUMP REPLACEMENT SHAFT SEAL &	P2131-3-9006
129.	PUMP, MANUAL HAND	P2131-3-0003
130.	SCREEN, GARDEN HOSE GASKET	P2131-3-3011
131.	STRAINER, SUCTION	P2131-3-3009
132.	WHEEL	P2131-3-5001
133.	WRENCH, SPANNER	P2131-3-1012

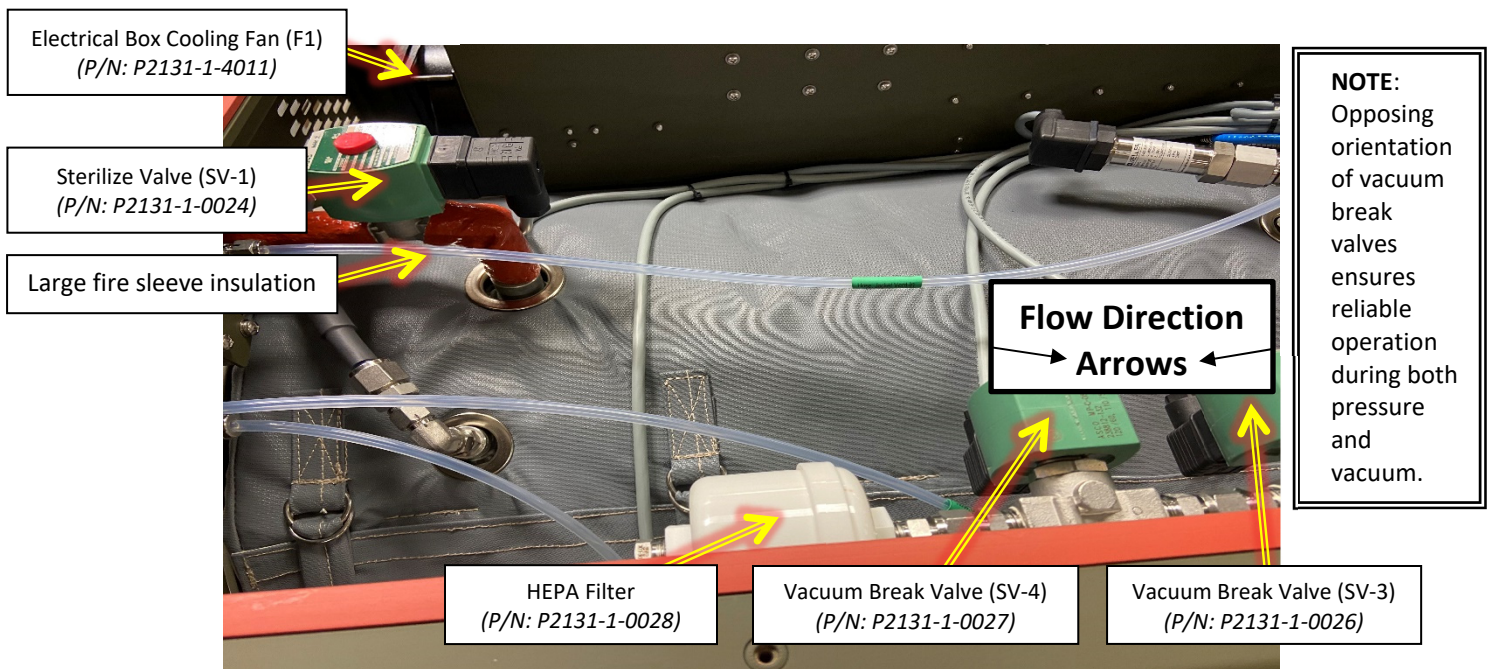
4.5 Interior Components Diagrams

NOTE: Nomenclature within parentheses is for reference on the Process Flow Diagram and Electrical Wiring Diagrams, sections 4.6 and 4.7 respectively.

Sterilizer Main Unit (SMU)

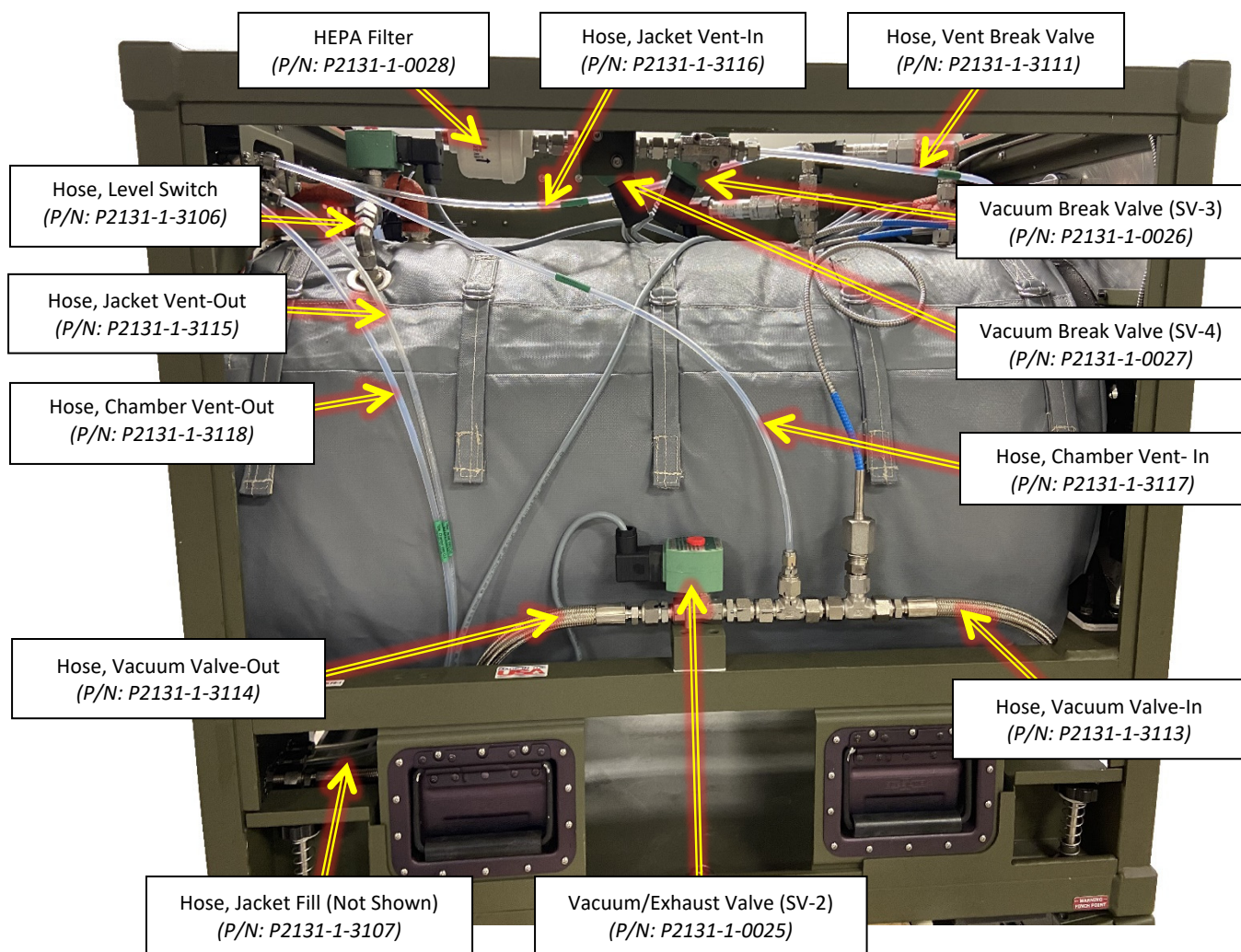


Top of SMU, from Left Side

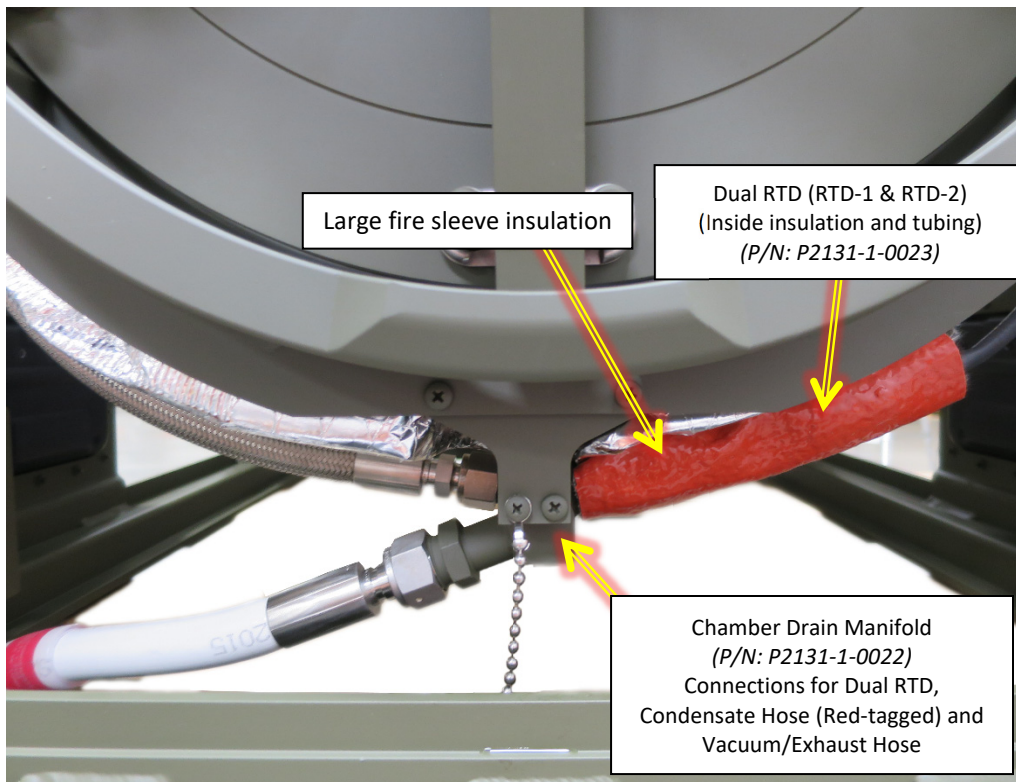


Back of SMU, from Left Side

NOTE: The Stainless-Steel braided hose used for **S/N's AFS-0001 through AFS-0354** has been changed to a clear PFA hose, starting with **S/N AFS-0355**. There are no changes to maintenance procedures or replacements of fittings. For future hose replacements, new PFA hose will be sent pre-swaged and ready for installation. Vacuum exhaust hoses from the chamber drain to the rear bulkhead remain the same.

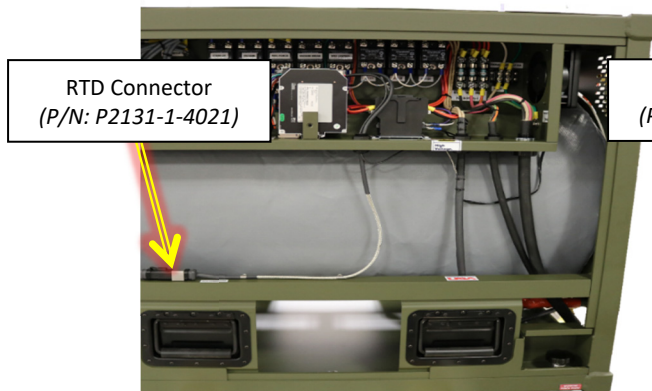


Left Side of SMU

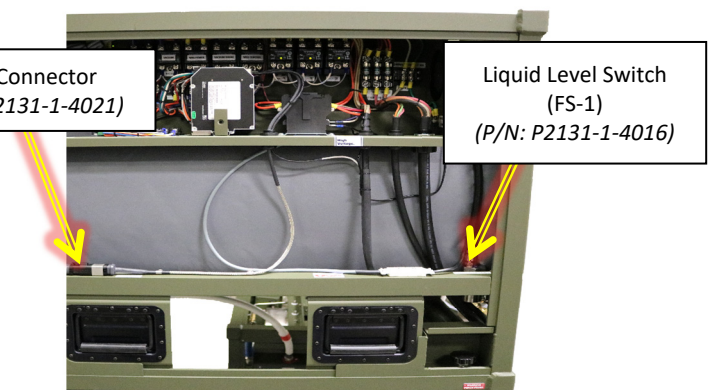


NOTE: A single sensor probe contains two RTD elements that are factory-calibrated and cannot be adjusted.

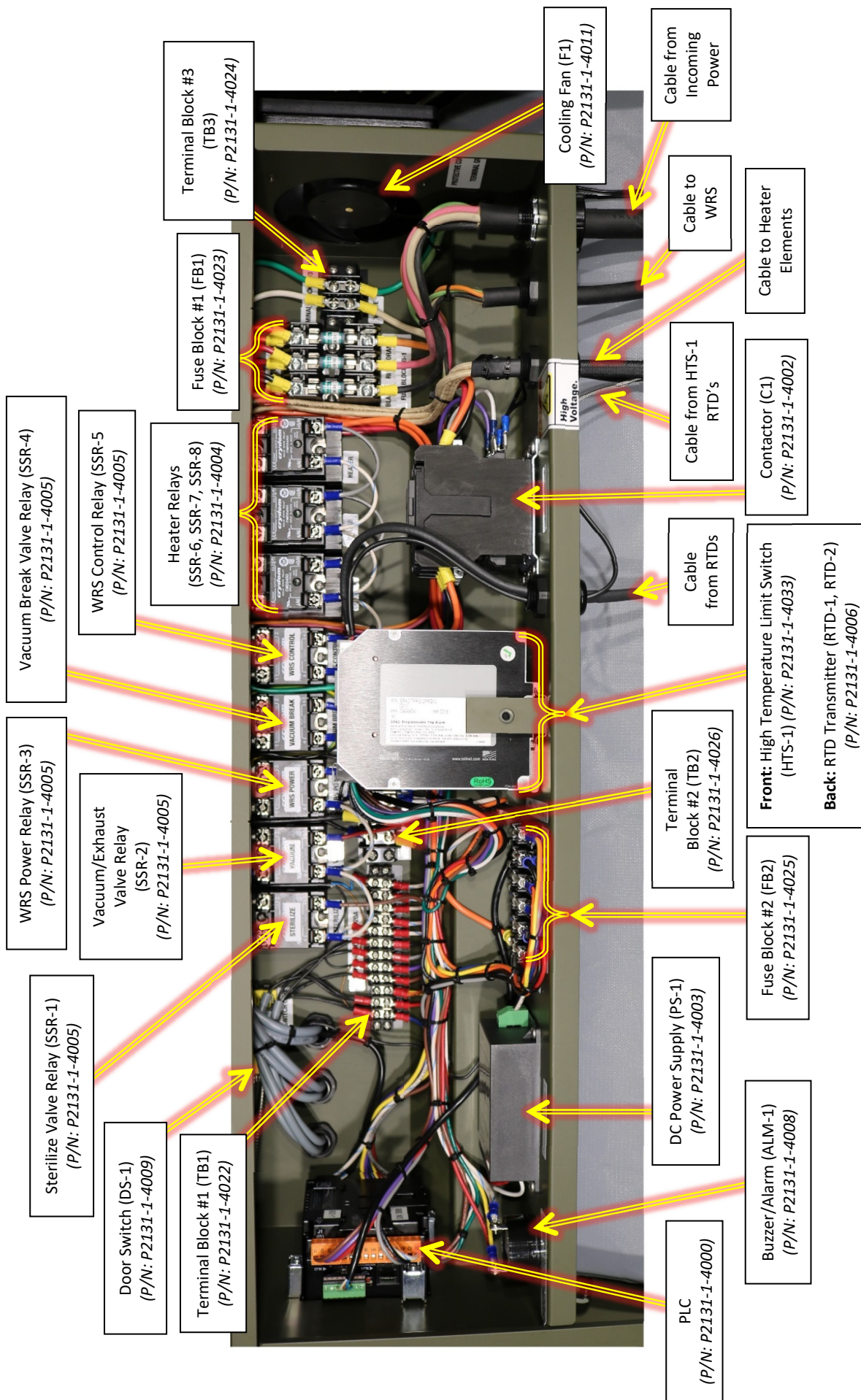
Front of SMU, behind Lower Front Panel



**Right Side of SMU for S/N's
AFS-0001 through AFS-0236**



**Right Side of SMU for S/N's
After AFS-0236**



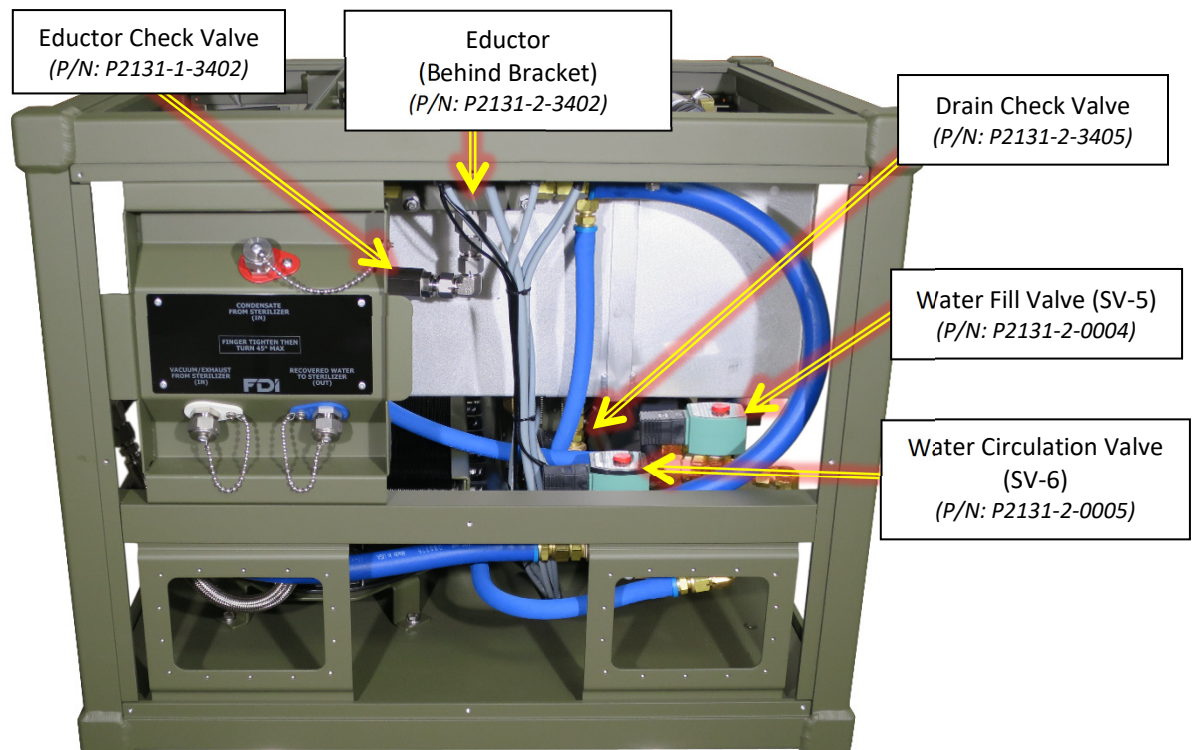
Electrical Box in SMU

Water Recovery System (WRS)

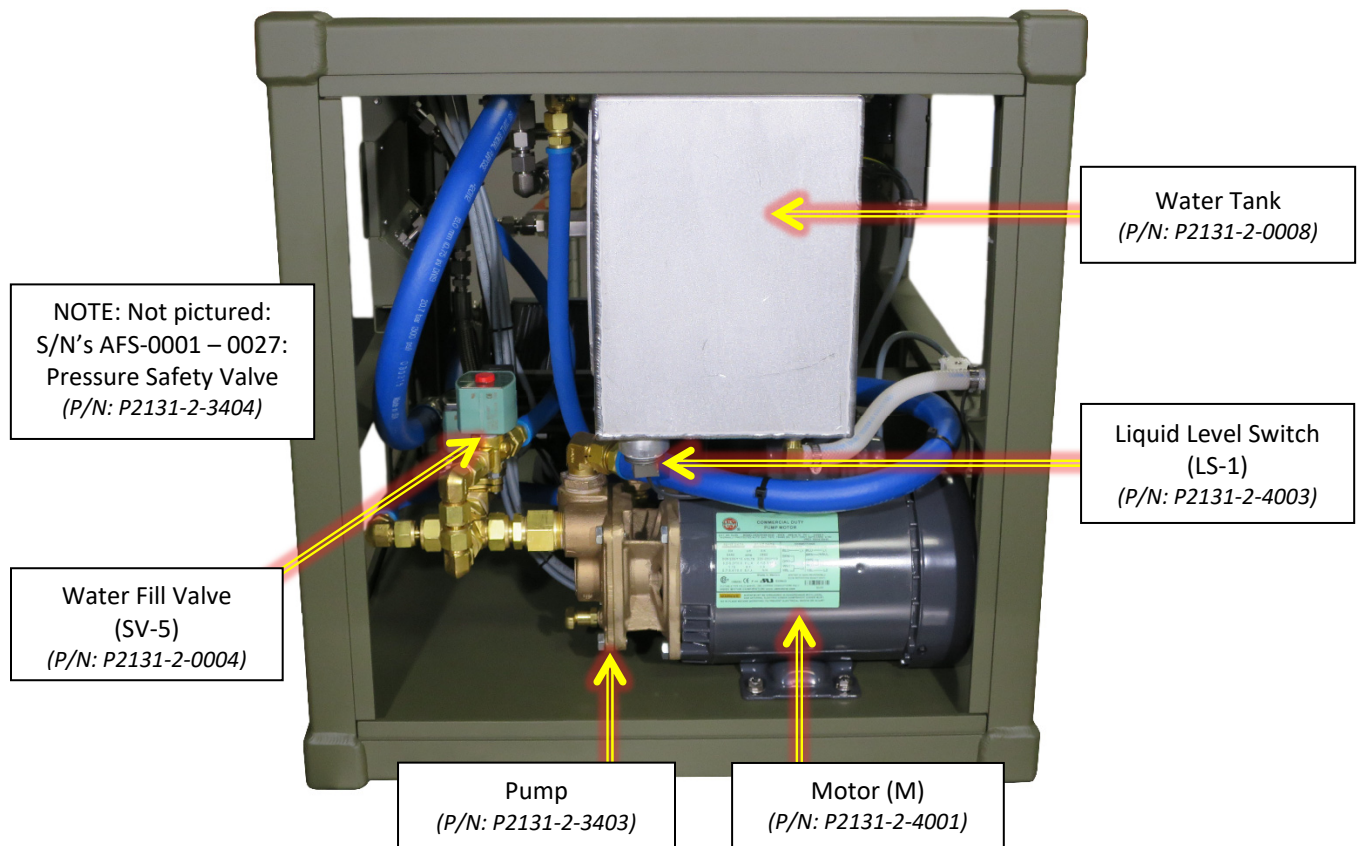
For S/N's AFS-0001 through AFS-0236:



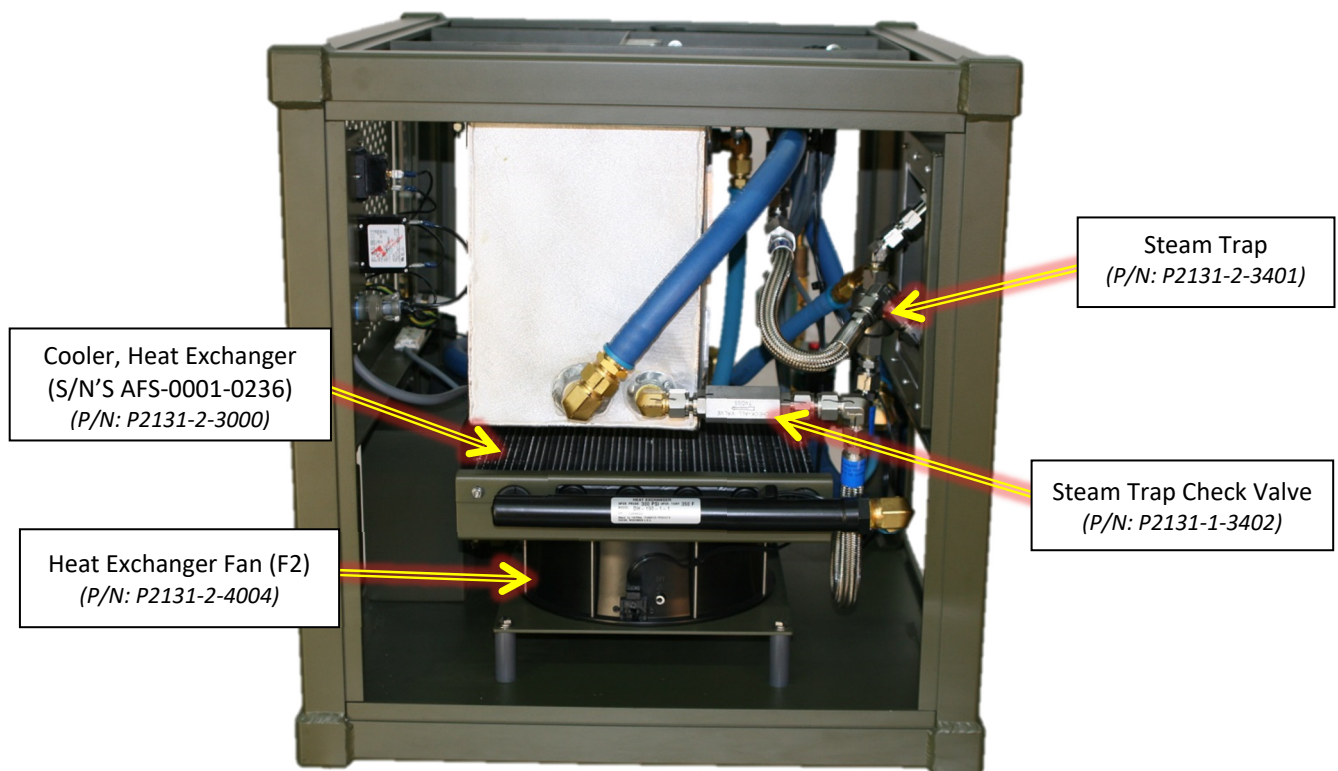
Right Side of WRS



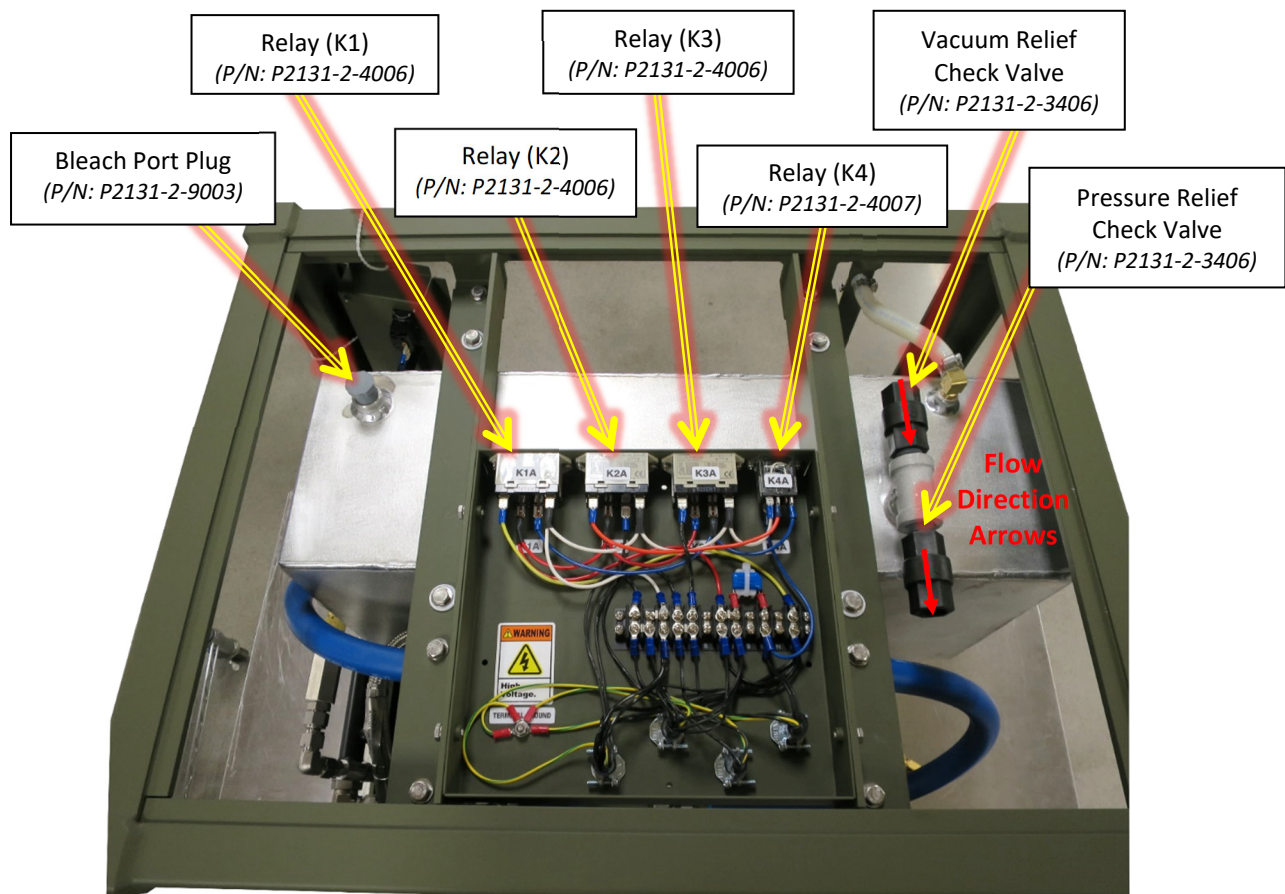
Left Side of WRS



Front of WRS



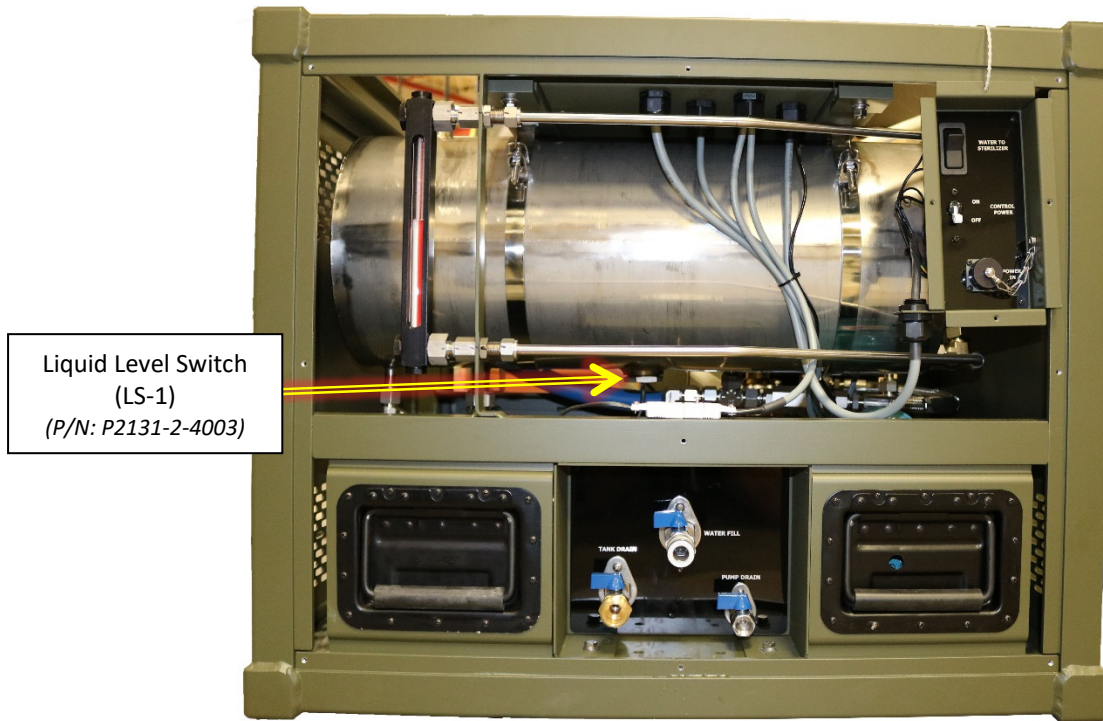
Back of WRS



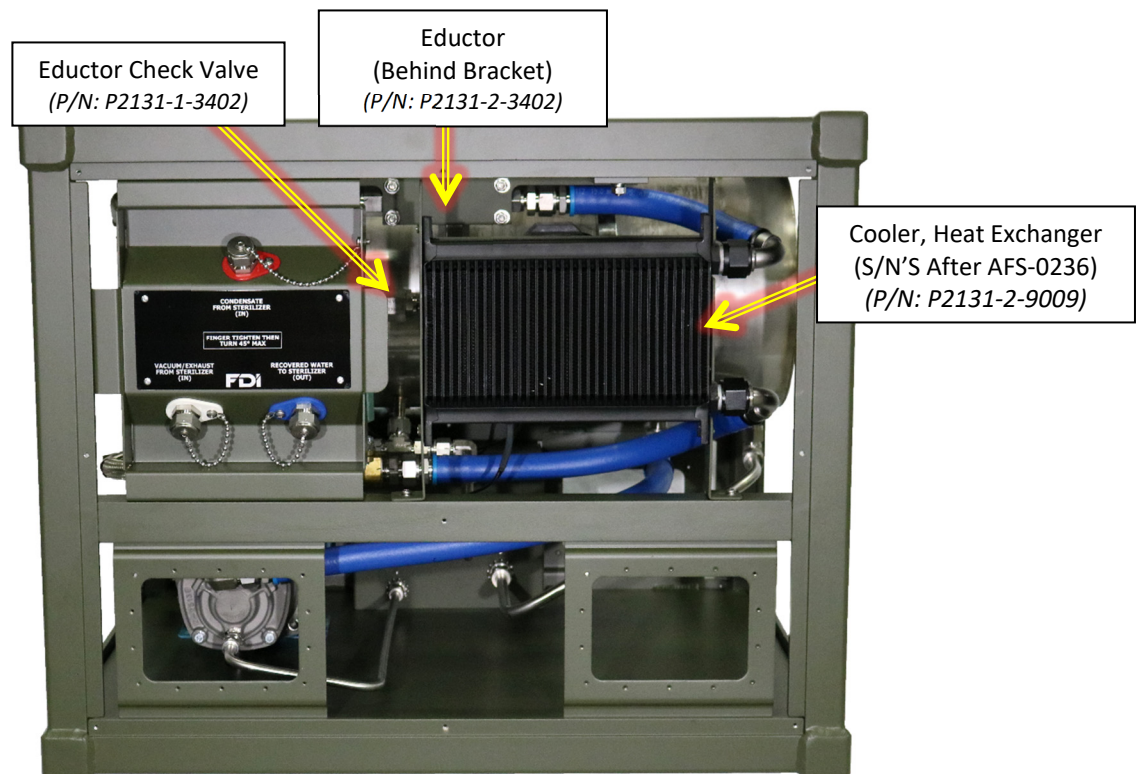
Top of WRS

Water Recovery System (WRS)

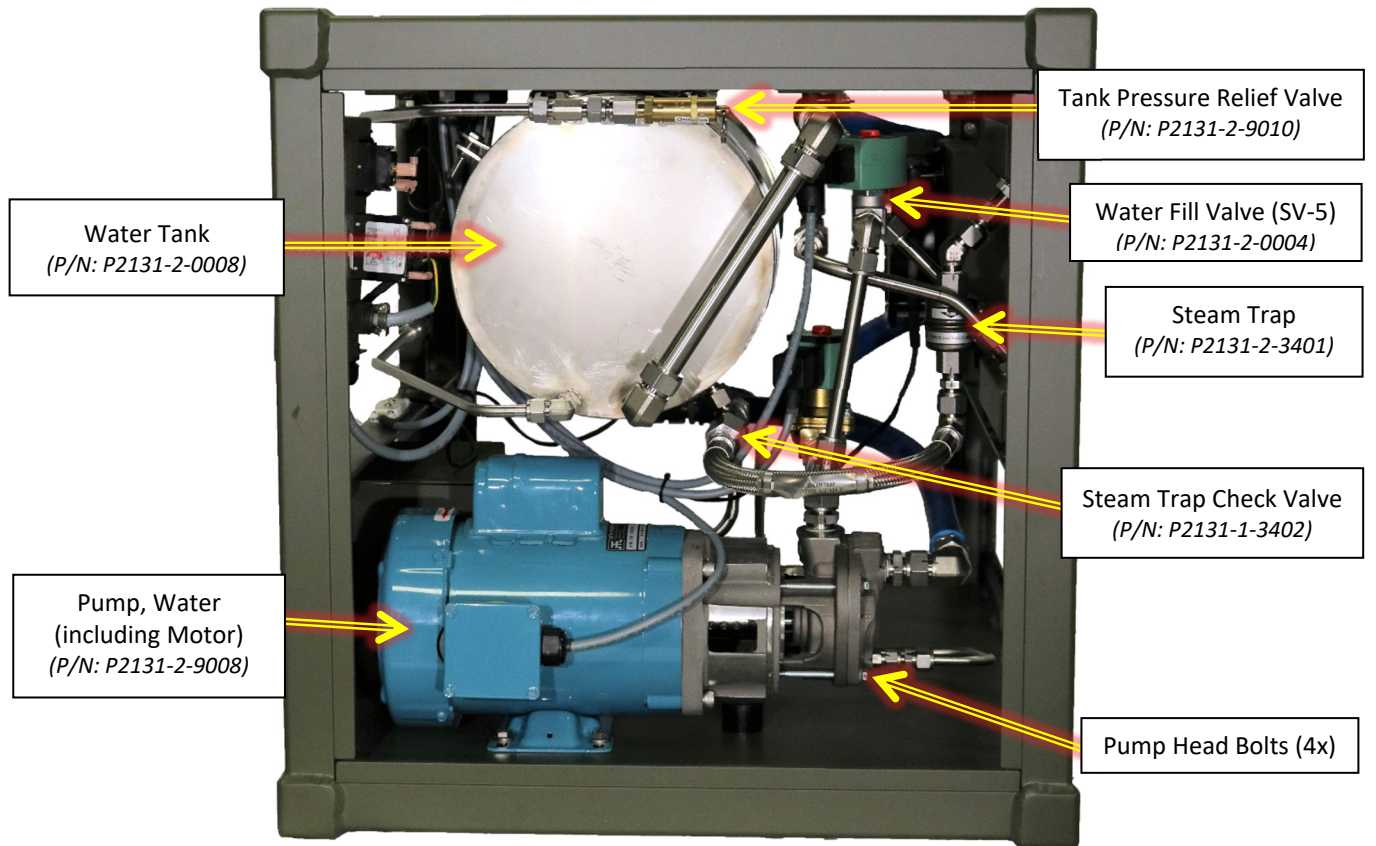
For S/N's after AFS-0236:



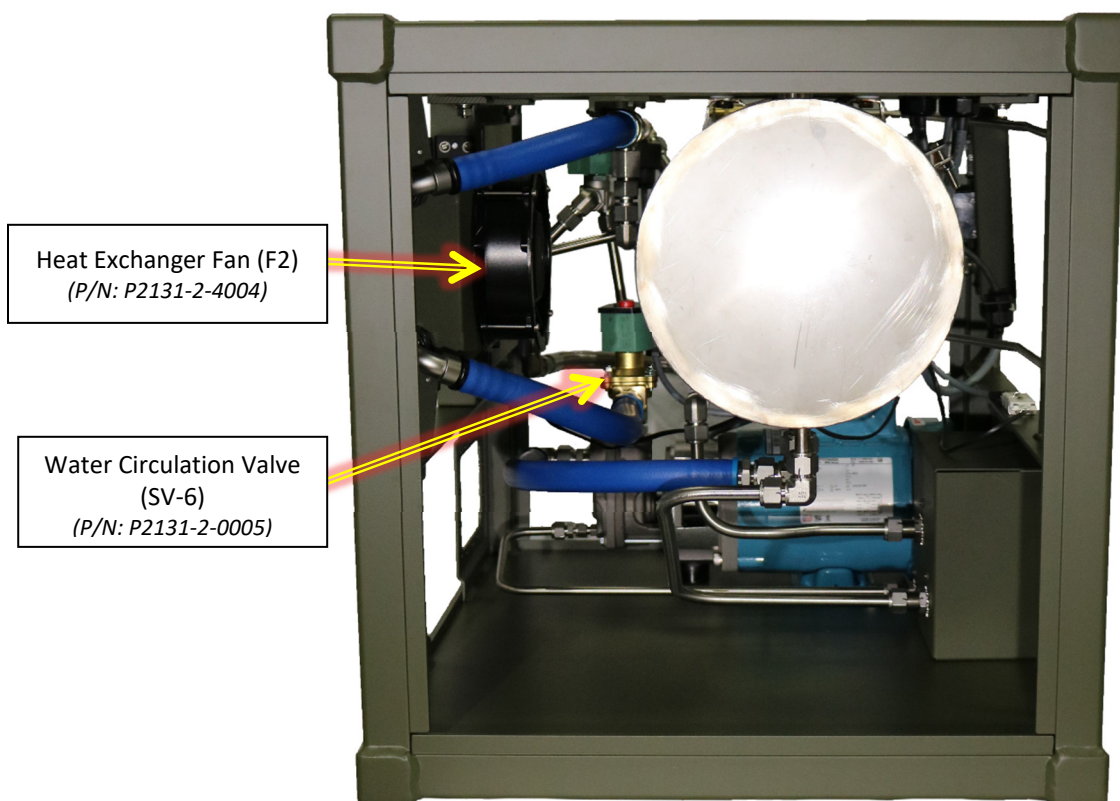
Right Side of WRS



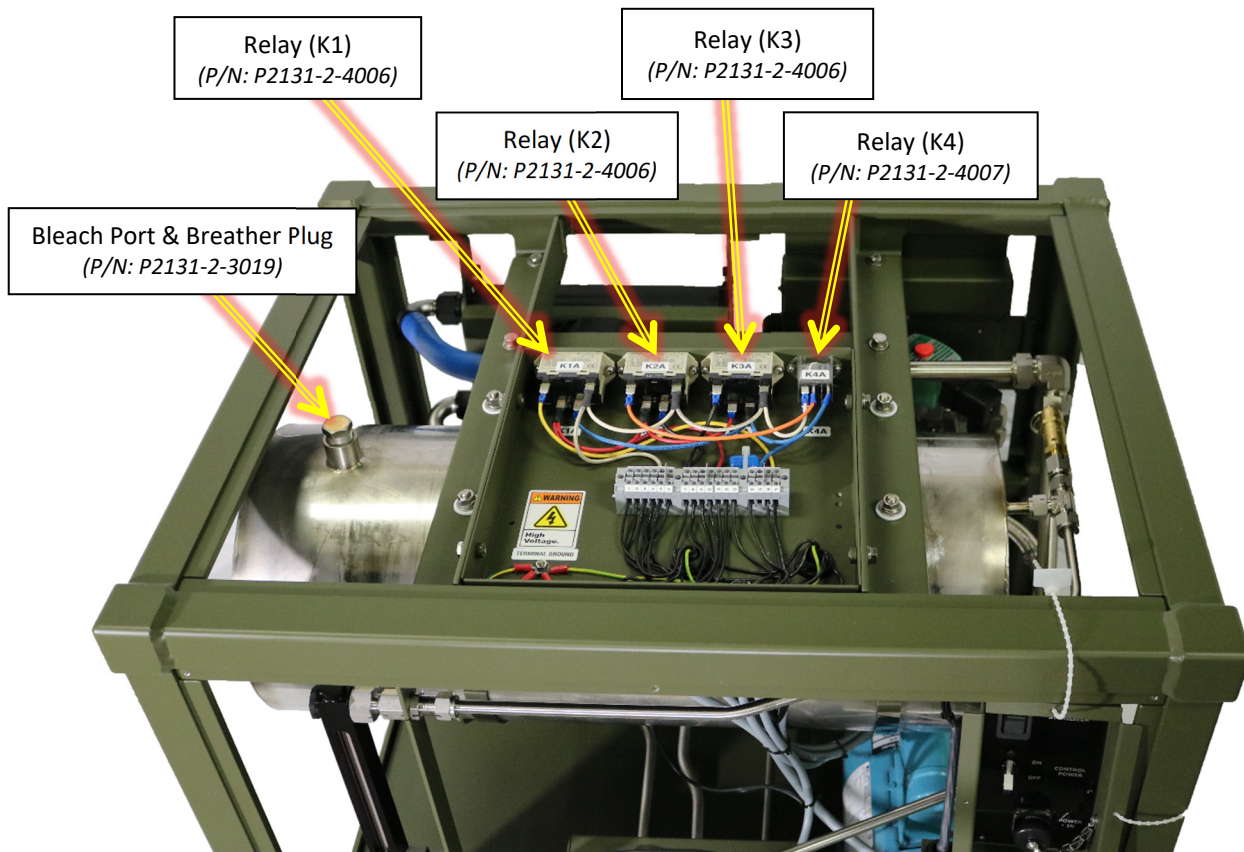
Left Side of WRS



Front of WRS



Back of WRS



Top of WRS

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4.6 Theory of Operation

4.6.1 Process Flow Description

Water enters the SWS housing by means of the Manual Water Pump or a pressurized water source. As water flows through the SWS, calcium, magnesium and other contaminants are removed. Water collects in the WRS Water Tank. This tank is equipped with a Liquid Level Switch (LS-1, normally closed) that will not allow the Pump to operate should the water reach a critically low level. When the user needs to pump water from the WRS up into the SMU Jacket (Boiler), the user depresses the Fill Switch (SW2), which activates the Pump. The Recirculation Valve (SV-6, normally open) closes and the Fill Valve (SV-5, normally closed) opens to allow the water to flow from the WRS Water Tank through the blue-tagged hose into the SMU Jacket.

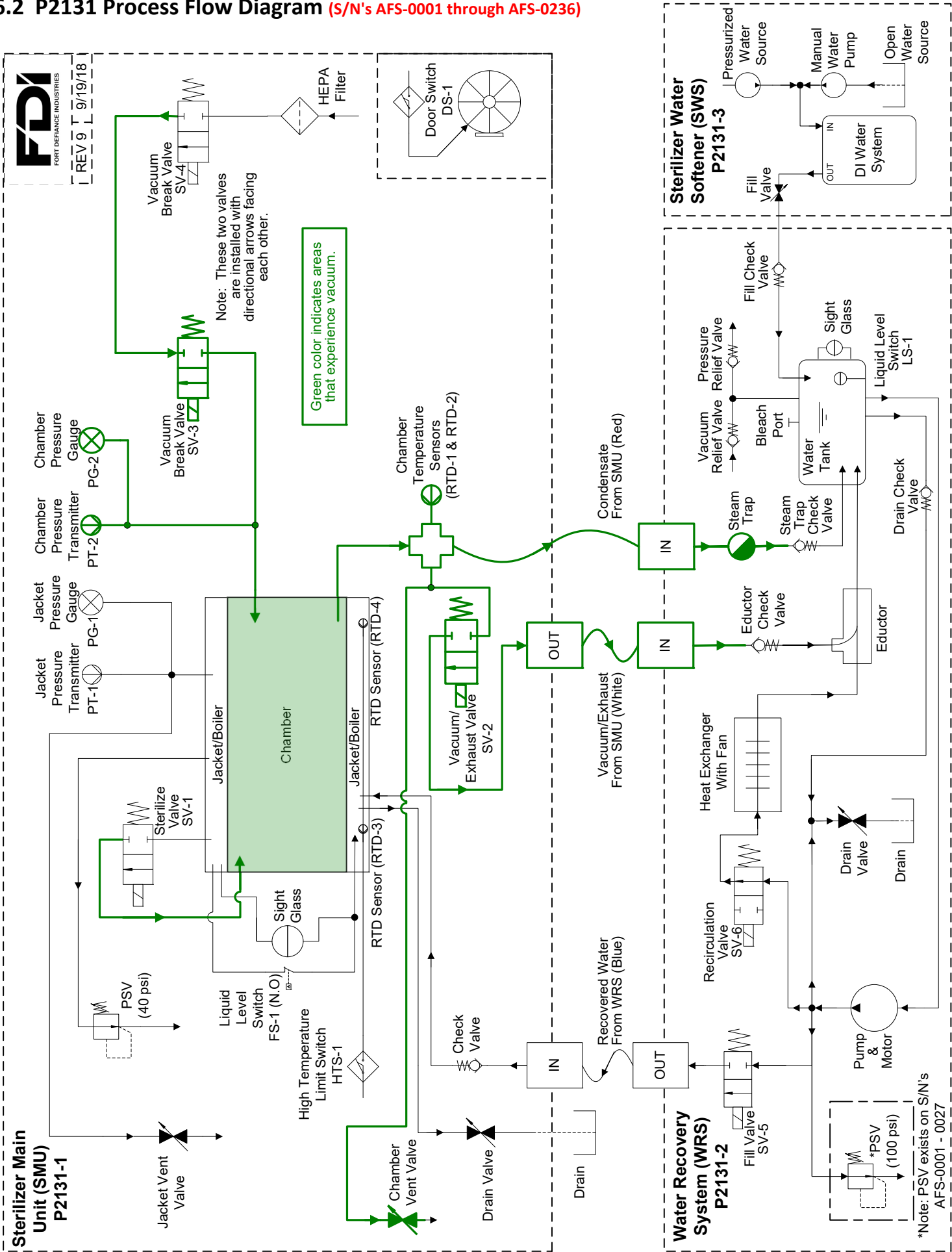
The Jacket is equipped with a Liquid Level Switch (FS-1, normally opened) which prevents the immersion heater elements from being energized if there is not enough water in the Jacket. In addition, as a secondary safeguard, the unit is equipped with a High Temperature Limit Switch (HTS-1, normally opened) to turn OFF power to the heaters and PLC. Once the user has pumped a sufficient amount of water into the Jacket, the Liquid Level Switch closes, allowing the SMU to operate and the immersion heater elements to turn ON/OFF by means of the programmable logic controller (PLC). As heat is supplied to the water in the Jacket, steam is generated and the pressure and temperature in the Jacket rises. The Jacket Pressure Transmitter (PT-1) supplies pressure data to allow the PLC to control the Jacket at a steady pressure set point when the Jacket is in pressure control (during idle and certain phases of a cycle).

The Door Switch (DS-1, normally open) will not allow a cycle to start (and steam to flow into the chamber) unless the door is closed and latched. When a cycle is started and steam is required in the Chamber, the Sterilize Valve (SV-1) is opened by the PLC to allow steam from the Jacket to flow into the Chamber. During the conditioning phase of a cycle, the Chamber Pressure Transmitter (PT-2) supplies pressure data to the PLC to allow it to pressurize or pull a vacuum in the Chamber to specific set points. When steam condenses during a cycle, it flows through the chamber drain, past the Chamber Temperature Sensors (RTD-1 & RTD-2), through the red-tagged hose, and finally through the WRS Steam Trap back into the Water Tank. The Chamber Temperature Sensors provide temperature data to allow the PLC to control the heater elements and maintain the Chamber at a steady temperature set point when the P2131 is in temperature control (during the heat-up and exposure phases of a cycle). The Steam Trap allows cool condensate to pass through to the WRS Water Tank but prevents the flow of steam.

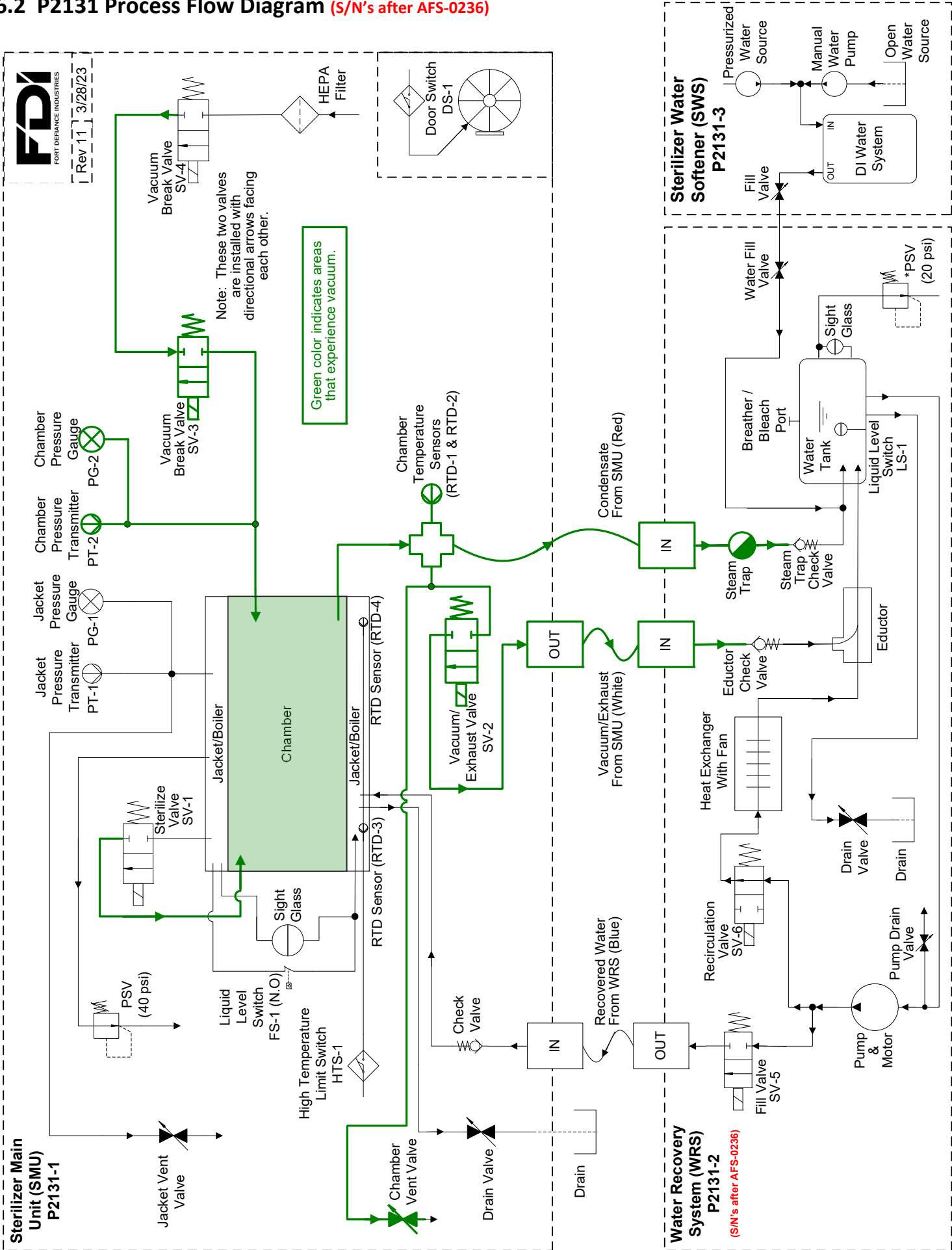
During the conditioning phase and the vent phase of a cycle, steam and/or air is evacuated from the Chamber. The PLC evacuates the Chamber by opening the Vacuum/Exhaust Valve (SV-2), allowing a venturi vacuum Eductor to pull the steam and/or air from the Chamber into the WRS via the white-tagged Vacuum/Exhaust hose. The steam/air is entrained in the water that flows through the Eductor back into the WRS Water Tank.

There are several cycles on the P2131 that require a drying phase after exposure. Since a vacuum facilitates faster drying, the PLC pulls a vacuum on the Chamber by opening the Vacuum/Exhaust Valve for the duration of the dry phase. After the dry phase, the PLC will equalize the pressure by opening the Vacuum Break Valves (SV-3/4) to allow outside air to be drawn through a HEPA filter into the Chamber. Once the Chamber Pressure Transmitter detects equalized pressure between the Chamber and outside environment, the PLC closes the Vacuum Break Valves, allowing the Chamber Door to be opened.

4.6.2 P2131 Process Flow Diagram (S/N's AFS-0001 through AFS-0236)

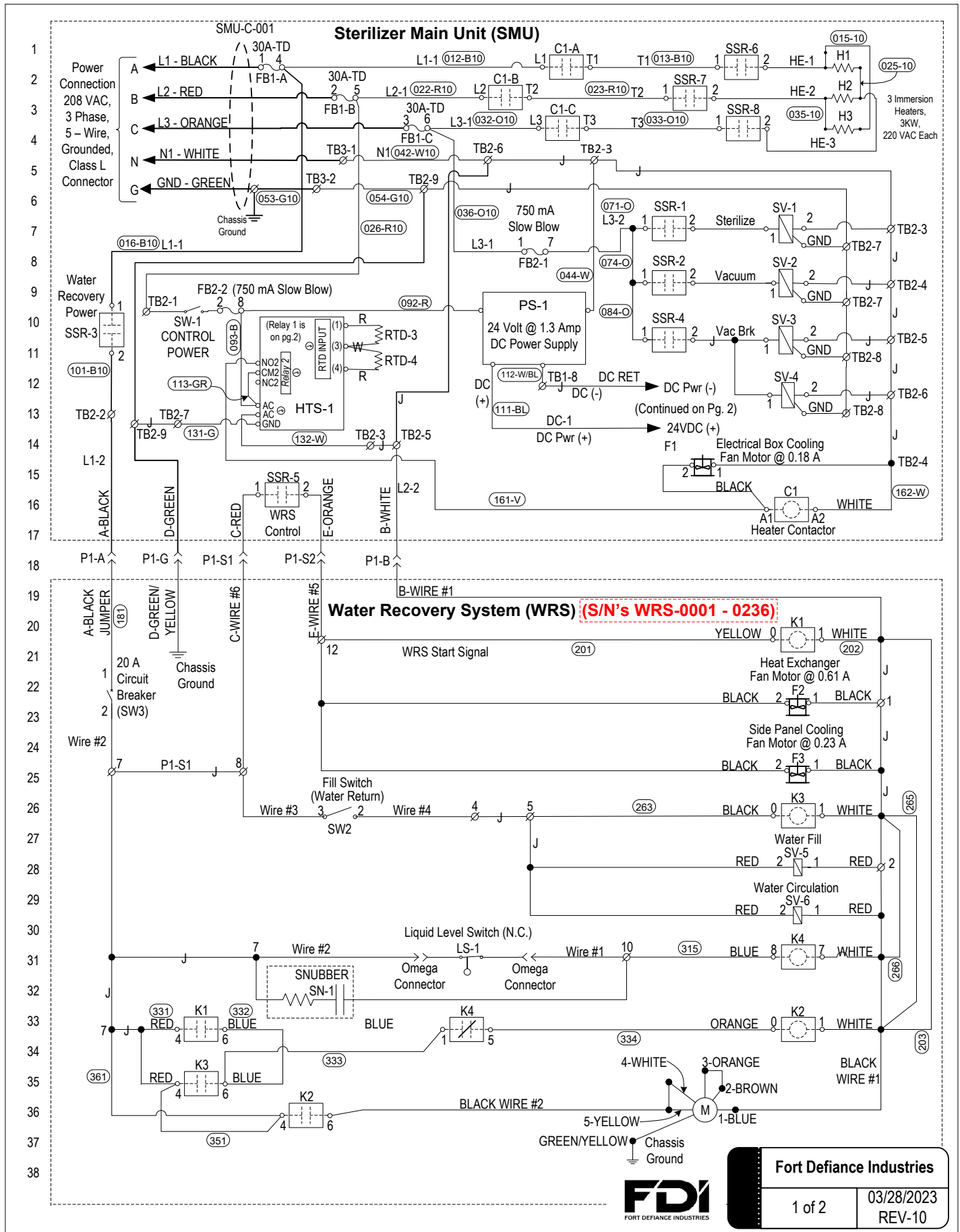


4.6.2 P2131 Process Flow Diagram (S/N's after AFS-0236)

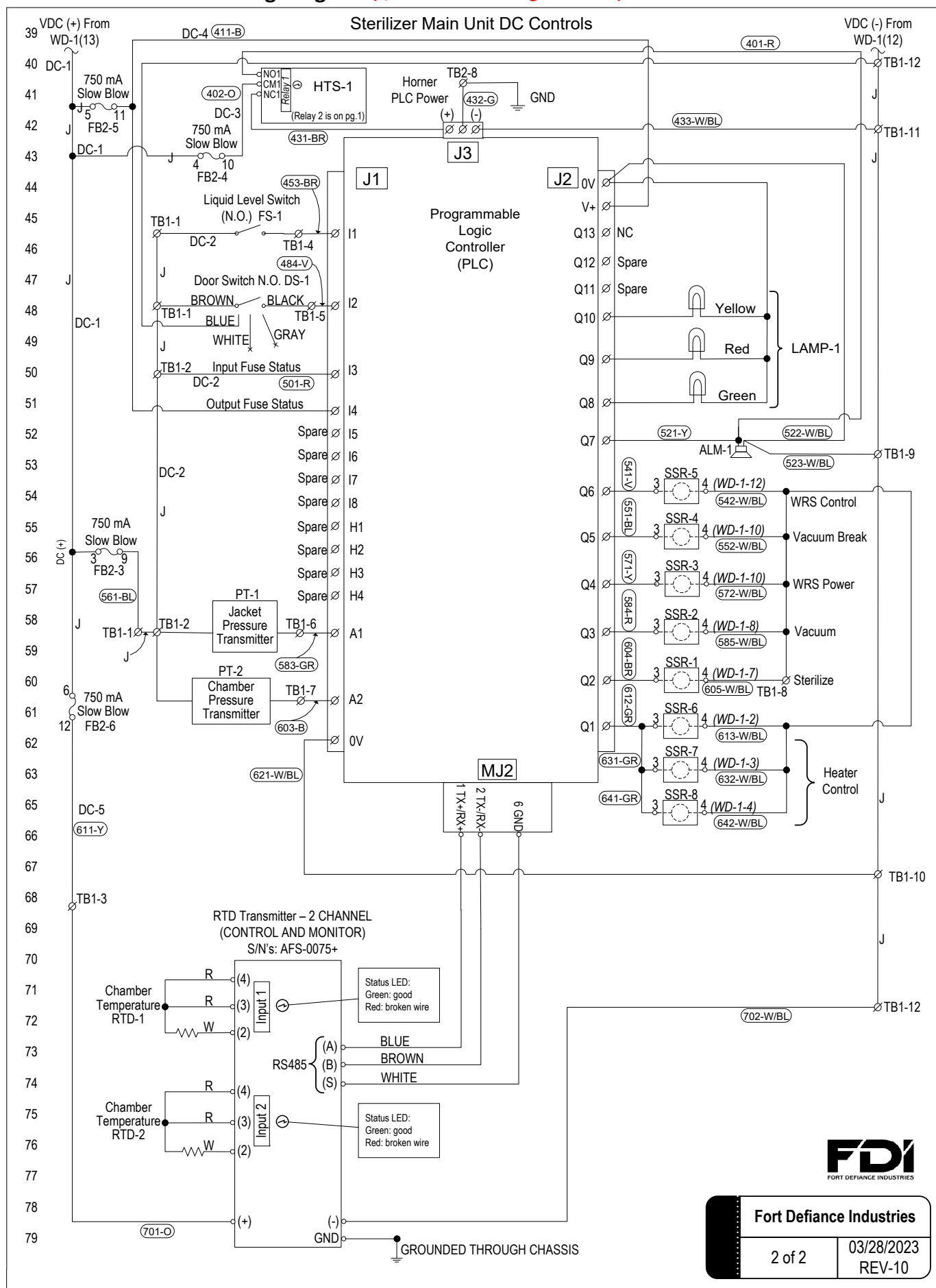


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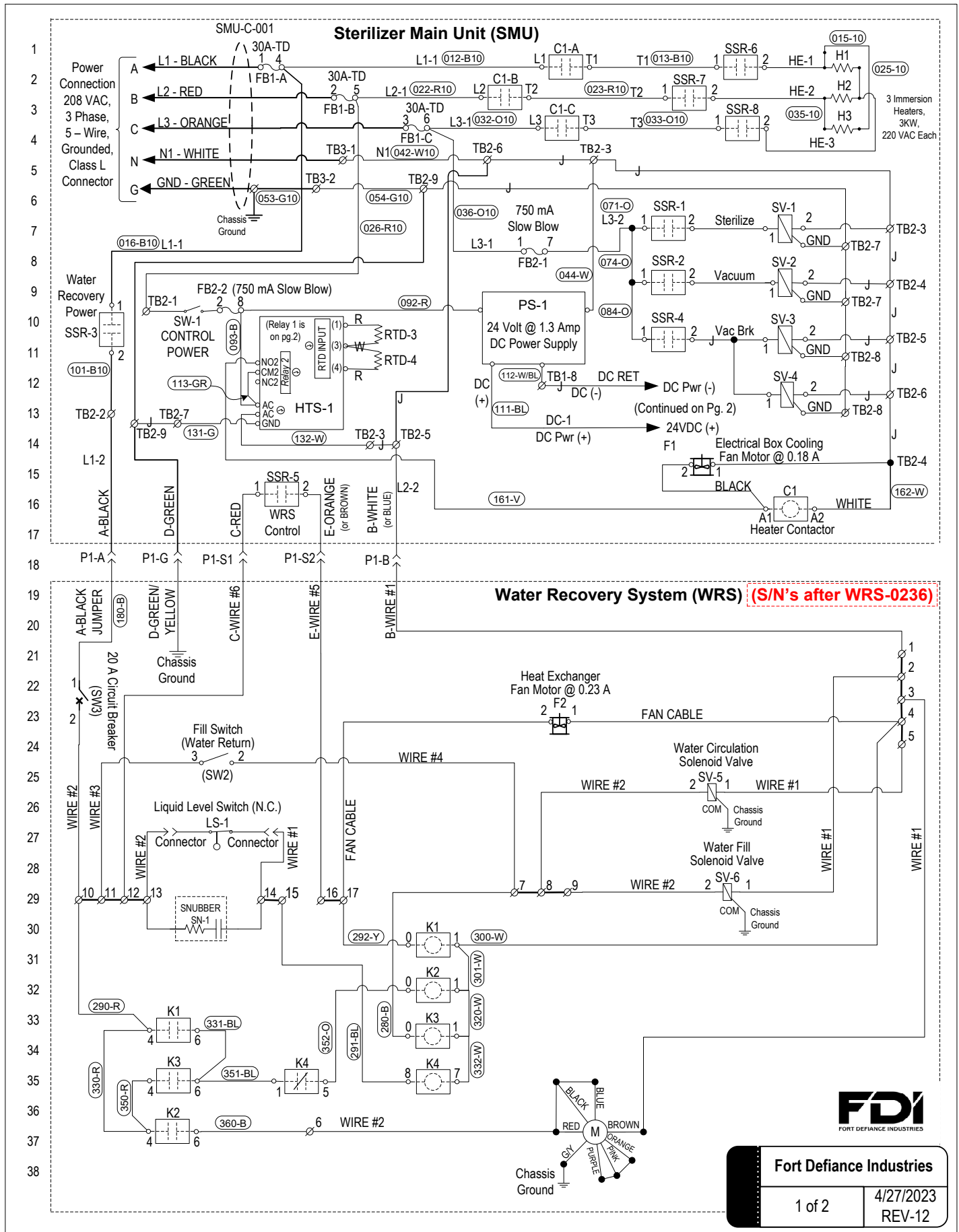
4.7 P2131 Electrical Wiring Diagram (S/N's AFS-0001 through AFS-0236)



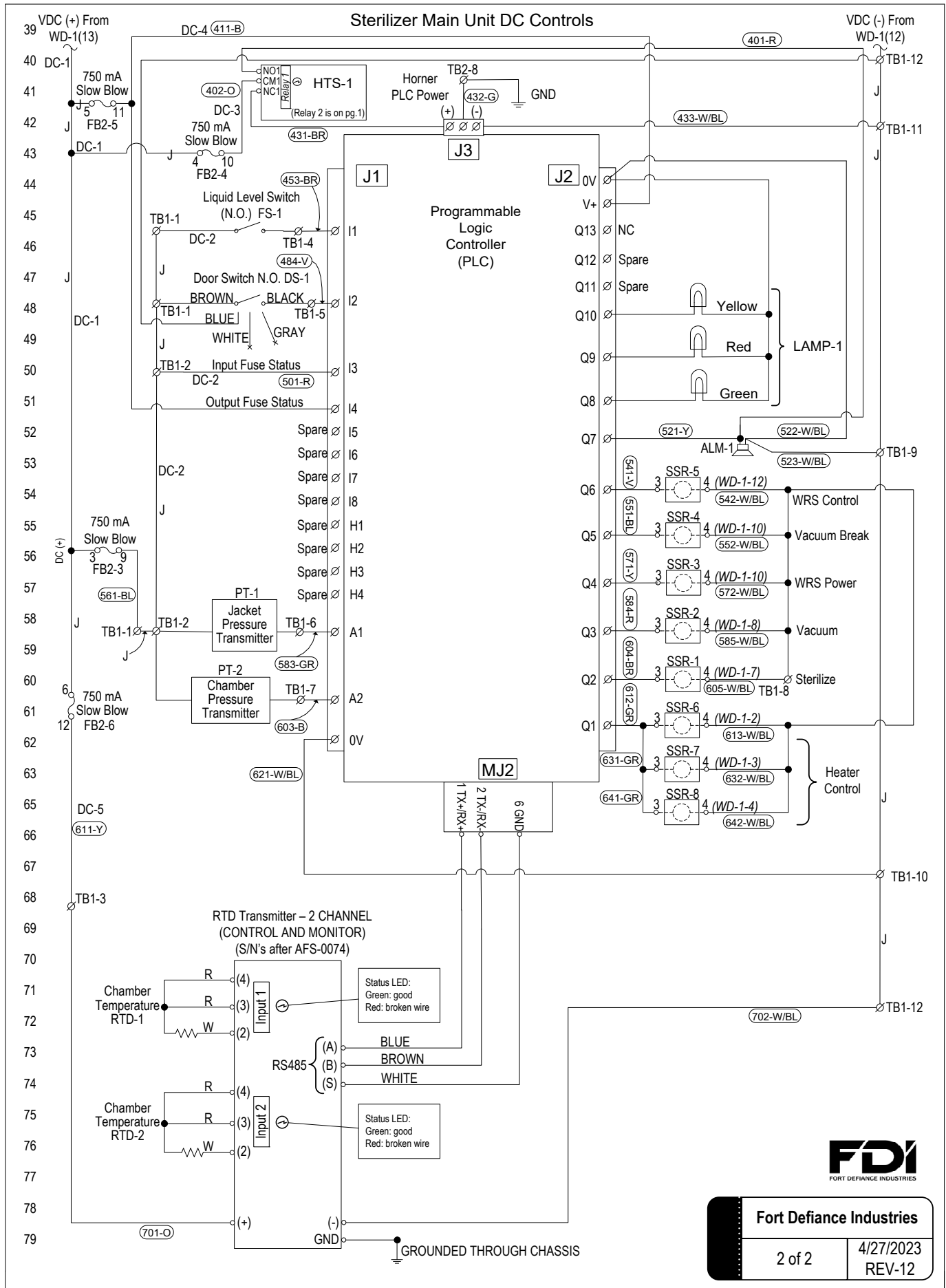
P2131 Electrical Wiring Diagram (S/N's AFS-0001 through AFS-0236)



4.7 P2131 Electrical Wiring Diagram (S/N's after AFS-0236)



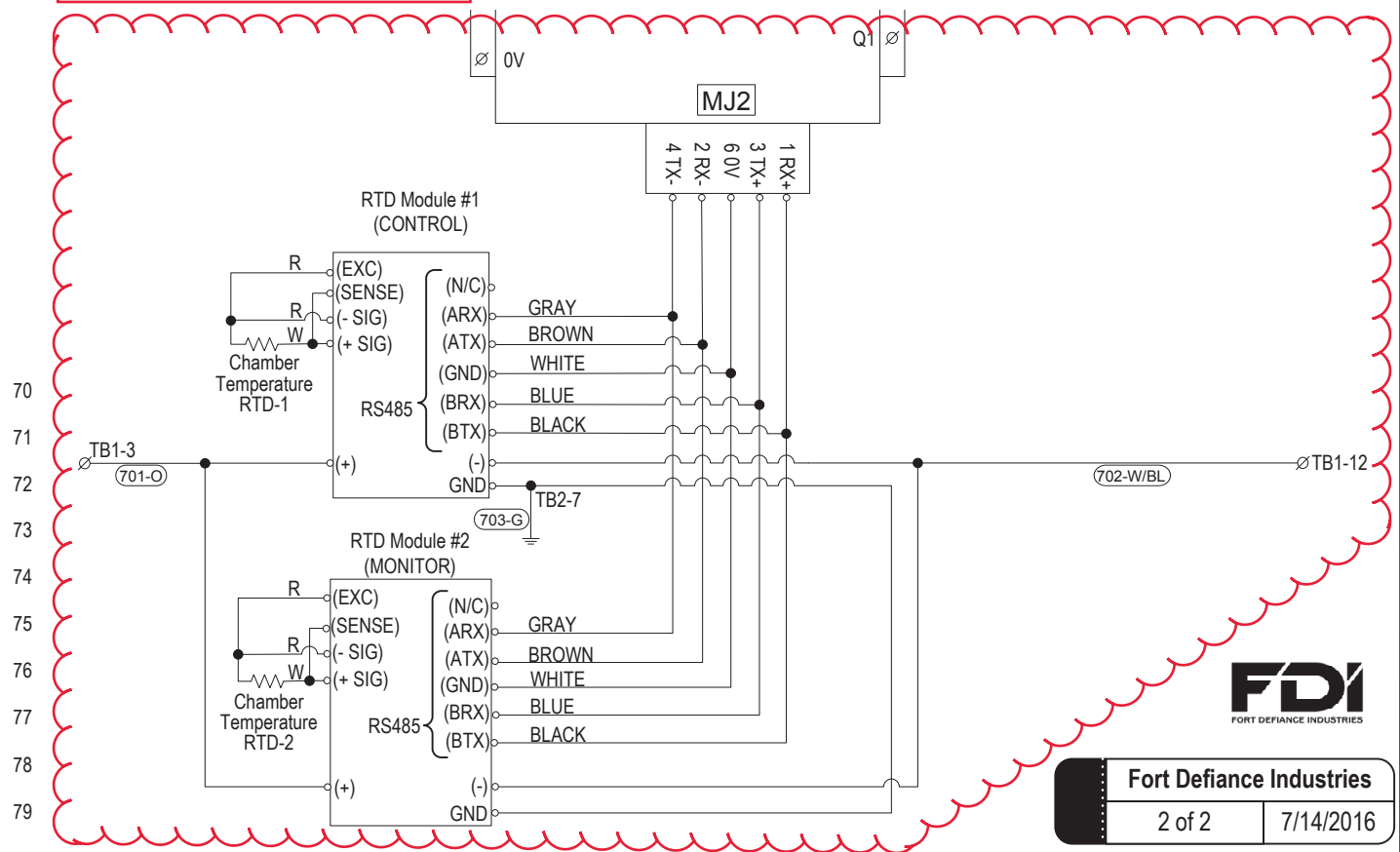
P2131 Electrical Wiring Diagram (S/N's after AFS-0236)



P2131 Electrical Wiring Diagram

Black RTD Transmitter (S/N's: AFS-0001 through AFS-0074)

S/N's: AFS-0001 - AFS-0074



SECTION A – APPENDIX

A.1 Swagelok Fitting Installation Instructions

INSTALLATION INSTRUCTIONS

Installation Instructions

Swagelok tube fittings 1 in./25 mm and smaller can be installed quickly, easily, and reliably with simple hand tools.

Over 1 in./25 mm sizes require use of a hydraulic swaging unit to swage the ferrules onto the tubing.

Safety Precautions

- Do not bleed system by loosening fitting nut or fitting plug.
- Do not assemble and tighten fittings when system is pressurized.
- Make sure that the tubing rests firmly on the shoulder of the tube fitting body before tightening the nut.
- Use the correct Swagelok gap inspection gauge to ensure sufficient pull-up upon initial installation.
- Always use proper thread sealants on tapered pipe threads.
- Do not mix materials or fitting components from various manufacturers—tubing, ferrules, nuts, and fitting bodies.
- Never turn fitting body. Instead, hold fitting body and turn nut.
- Avoid unnecessary disassembly of unused fittings.
- Use only long reducers in female Swagelok end connections.

See the instructions starting below for installation of Swagelok tube fittings, O-seal male connectors, caps and plugs, port connectors, tube adapters, positionable elbows and tees, weld fittings, depth marking tool, and preswaging tool.

9

INSTALLATION INSTRUCTIONS

Swagelok Tube Fittings

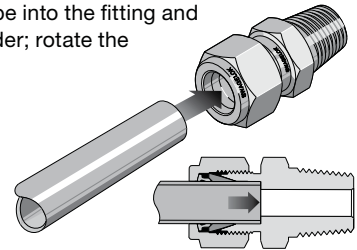
Up to 1 in./25 mm

These instructions apply both to traditional fittings and to fittings with the advanced back-ferrule geometry.

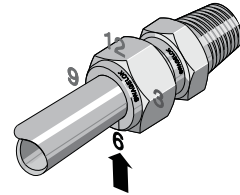
Fully insert the tube into the fitting and against the shoulder; rotate the nut finger-tight.

High-pressure applications and high safety-factor systems:

Further tighten the nut until the tube will not turn by hand or move axially in the fitting.

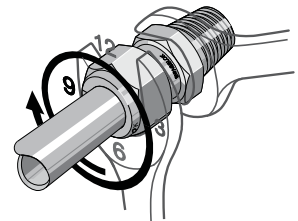


Mark the nut at the 6 o'clock position.



While holding the fitting body steady, tighten the nut one and one-quarter turns to the 9 o'clock position.

For 1/16, 1/8, and 3/16 in.; 2, 3, and 4 mm tube fittings, tighten the nut three-quarters turn to the 3 o'clock position.



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INSTALLATION INSTRUCTIONS

Swagelok Tube Fittings

Over 1 in./25 mm

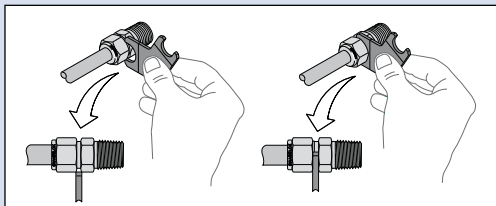
1. Preswage the ferrules onto the tube using a Swagelok multihead hydraulic swaging unit (MHSU).
2. Apply the lubricant packaged with the fitting lightly to the body threads and the rear surface of the back ferrule.
3. Insert the tube with preswaged ferrules into the fitting until the front ferrule seats against the fitting body; rotate the nut finger-tight.
4. Mark the nut at the 6 o'clock position.
5. While holding the fitting body steady, tighten the nut one-half turn to the 12 o'clock position.

Use the Swagelok MHSU gap inspection gauge to ensure that the fitting has been tightened sufficiently.

Gaugeability

On initial installation, the Swagelok gap inspection gauge assures the installer or inspector that a fitting has been sufficiently tightened.

Position the Swagelok gap inspection gauge next to the gap between the nut and body.



If the gauge **will not** enter the gap, the fitting is sufficiently tightened.

If the gauge **will** enter the gap, additional tightening is required.

⚠ Always depressurize a system before adjusting the tightness of a tube fitting connection.

11

INSTALLATION INSTRUCTIONS

Swagelok Tube Fittings

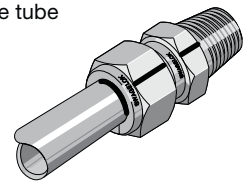
Reassembly—All Sizes

You may disassemble and reassemble Swagelok tube fittings many times.

⚠ Always depressurize the system before disassembling a Swagelok tube fitting.

Prior to disassembly, mark the tube at the back of the nut; mark a line along the nut and fitting body flats.

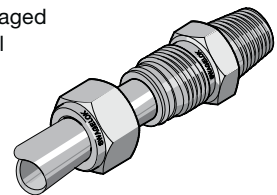
Use these marks to ensure that you return the nut to the previously pulled-up position.



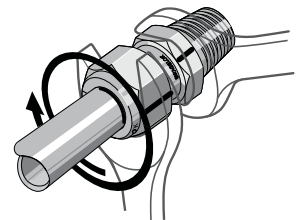
Insert the tube with preswaged ferrules into the fitting until the front ferrule seats against the fitting body.

Over 1 in./25 mm sizes:

If needed, reapply lubricant lightly to the body threads and the rear surface of the back ferrule.



While holding the fitting body steady, rotate the nut with a wrench to the previously pulled-up position, as indicated by the marks on the tube and flats. At this point, you will feel a significant increase in resistance. Tighten the nut slightly.



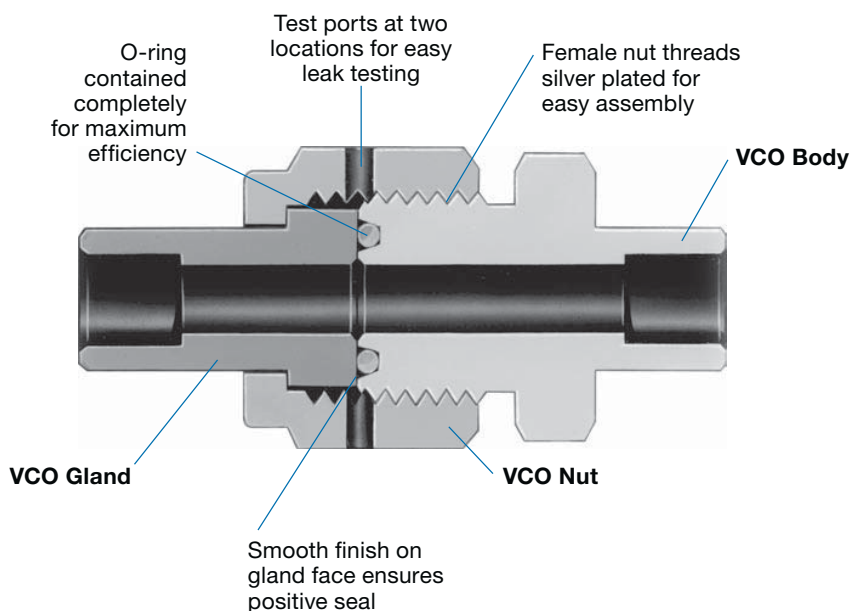
⚠ Do not use the Swagelok gap inspection gauge with reassembled fittings.

12

Features

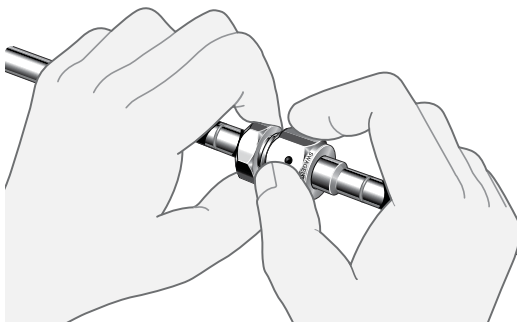
Swagelok VCO O-ring face seal fittings are designed for rapid assembly in pipe, tube, and welded systems.

- Unique design allows easy installation where space is limited.
- No axial clearance is required.
- Sealing is accomplished with a captive O-ring in the body component.
- Assemblies can be used from high pressure to critical vacuum, within a wide range of temperatures.

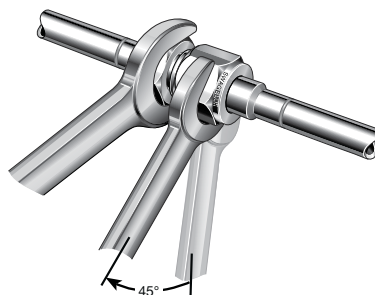


VCO Fitting Installation Instructions

1 Finger-tight



2



A.2 PLC Data Sheet



XLE MODEL

XLE & XLT OCS DATASHEET

MODEL 3

12 DC In, 12 DC Out, 2 - 12-bit Analog In



XLT MODEL

1 TECHNICAL SPECIFICATIONS

1.1 General

Typical power-backlight 100%	164mA @ 10V (1.64W) 116mA @ 24V (2.77W)
Power Backlight Off	-15mA @ 24V (0.36W)
Power Ethernet Models	+35mA @ 10V (0.35W) +20mA @ 24V (0.48W)
Inrush Current	30A for < 1mS
Primary Pwr. Range	10-30VDC
Real Time Clock	Yes, battery backed; lithium coin cell CR2450
Clock Accuracy	+/- 90 Secs/Month
Relative Humidity	5 to 95% Non-condensing
Operating Temp.	-10°C to +60°C
Storage Temp.	-20°C to +70°C
Weight	0.75 lbs/340g (without I/O)
Certifications (UL/CE)	USA: https://hornerautomation.com/certifications/ Europe: http://www.horner-apg.com/en/support/certification.aspx

1.2 User Interface

Display Type	Transflective LCD (outdoor readable)
Resolution	128 x 64 pixels (XLe) 160 x 128 pixels (XLT)
Color	Monochrome
Built-In Storage	16MB
User-Program. Screens	1023 max 50 Objects per page
Backlight	LED
Backlight Lifetime	30,000+hrs
Brightness Control	0-100%(Xlt) On/Off(X- le) via system register
Screen Update Rate	Program dependant
Number of Keys	20 (XLe) 5 (XLT)
Touchscreen (XLT)	Resistive 1,000,000+ touch life

1.3 Connectivity

Serial Ports	RS-232 full handshaking or RS-485 half duplex on first Modular Jack (MJ1) RS-232 or RS-485 on second Modular Jack (MJ2)
USB mini-B	Programming only
CAN	1x CAN Port, Isolated 1KV
CAN Protocols	CsCAN, CANopen, DeviceNet, J1939
Ethernet	Ethernet versions only
Ethernet Protocols	TCP/IP, Modbus TCP, FTP, SRTP, EGD, ICMP, ASCII
Remote I/O	SmartRail, SmartStix, SmartBlock, SmartMod
Removable Memory	MicroSD (SDHC, SDXC IN FAT32 format, support for 32GB max. Application Updates, Datalogging, more
Audio (XLT only)	Beeper, System or Software Controlled

1.4 Control & Logic

Control Lang. Support	Advanced Ladder Logic Full IEC 61131-3 Languages
Logic Program Size	256KB
Scan Rate	0.7 mS/K logic (XLe) 0.8 mS/K logic (XLT)
Digital Inputs	2048
Digital Outputs	2048
Analog Inputs	512
Analog Outputs	512
Gen. Purpose Registers	9,999 (words) Retentive 2,048 (bits) Retentive 2,048 (bits) Non-retentive

1.5 Inputs/Outputs

Model	DC In	DC Out	Relays	HS In	HS Out	mA/V In	mA/V RTD/T	mA/V Out
Model 0	-	-	-	-	-	-	-	-
Model 2	12	-	6	4	-	4	-	-
Model 3	12	12	-	4	2	2	-	-
Model 4	24	16	-	4	2	2	-	-
Model 5	12	12	-	4	2	-	2	2
Model 6	12	12	-	4	2	-	6	4

There are 4 high-speed inputs of the total DC Inputs. There are 2 high-speed outputs of the total DC outputs. Model 2, 3 & 4 feature 12-bit Analog Inputs. Model 5 features 14/16-bit Analog Inputs. High-speed Outputs can be used for PWM and Pulse Train Outputs, currently limited to <10kHz. (Model 6 limited to <65kHz). Model 6 features a 16 bit Analog Input.

High-Speed Inputs		High-Speed Outputs	
Number of Counters	4	Modes Supported	Stepper, PWM
Maximum Frequency	500 kHz each		
Accumulator Size	32-bits each		
Modes Supported	Totalizer, quadrature, pulse measurement, frequency measurement, set-point controlled outputs		

technical specifications continued...

1.6 Digital DC Inputs

Inputs per Module	12 Including 4 Configurable HSC Inputs	
Commons per Module	1	
Input Voltage Range	12 VDC / 24 VDC	
Absolute Max. Voltage	35 VDC Max.	
Input Impedance	10 kΩ	
Input Current: Upper Threshold Lower Threshold	Positive Logic: 0.8 mA 0.3 mA	Negative Logic: -1.6 mA -2.1 mA
Max. Upper Threshold	8 VDC	
Min. Lower Threshold	3 VDC	
OFF to ON Response	1 mS	
ON to OFF Response	1 mS	
High Speed Counter Max Freq*	500 kHz	

*See I/O info below for detail regarding HSC and PWM

1.7 Digital DC Outputs

Outputs per Module	12 Including 2 Configurable PWM Outputs
Commons per Module	1
Output Type	Sourcing / 10 kΩ Pull-Down
Absolute Max. Voltage	28 VDC Max.
Output Protection	Short Circuit
Max. Output Current/Point	0.5 A
Max. Total Current	4 A Continuous
Max. Output Supply Voltage	30 VDC
Min. Output Supply Voltage	10 VDC
Max. Voltage Drop at Rated Current	0.25 VDC
Max. Inrush Current	650 mA per Channel
Min. Load	None
OFF to ON Response	1 mS
ON to OFF Response	1 mS
PWM Out	10 kHz
Output Characteristics	Current Sourcing (Pos. Logic)

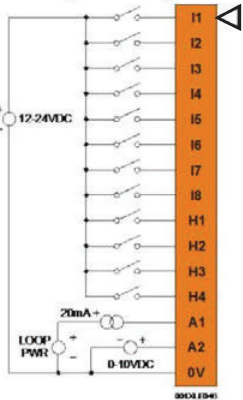
1.8 Analog Outputs

Number of Channels	2
Input Ranges Safe Input Range Input Impedance (Clamped @ -0.5 VDC to 12 VDC)	0 - 10 VDC 0 - 20 mA 4 - 20 mA -0.5 V to +12V Current Mode: 100Ω Voltage Mode: 500Ω
Nominal Resolution %AI full scale Max. Over-Current	10 Bits 32,000 counts 35 mA
Conversion Speed	All channels converted once per ladder scan
Max. Error @25° C (excluding zero)	4-20 mA 1.00% 0-20 mA 1.00% 0-10 VDC 0.50%
Filtering	160 Hz hash (noise) filter 1128 scan digital running average filter

1.9 J1 (Orange) Name

I2	IN1
I2	IN2
I3	IN3
I4	IN4
I5	IN5
I6	IN6
I7	IN7
I8	IN8
H1	HSC1 / IN9
H2	HSC2 / IN10
H3	HSC3 / IN11
H4	HSC4 / IN12
A1	Analog IN1
A2	Analog IN2
OV	Common

J1 (Orange) Positive Logic
Digital & Analog In



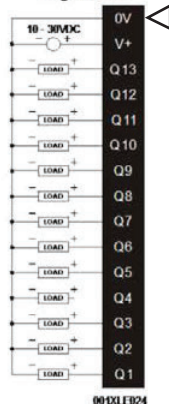
Wiring Details:

Solid/Stranded wire - 12-24 awg (2.5-0.2mm²).
Strip length - 0.28" (7mm).
Torque rating: 4.5 - 7 lb-in (0.50 - 0.78 N-m).

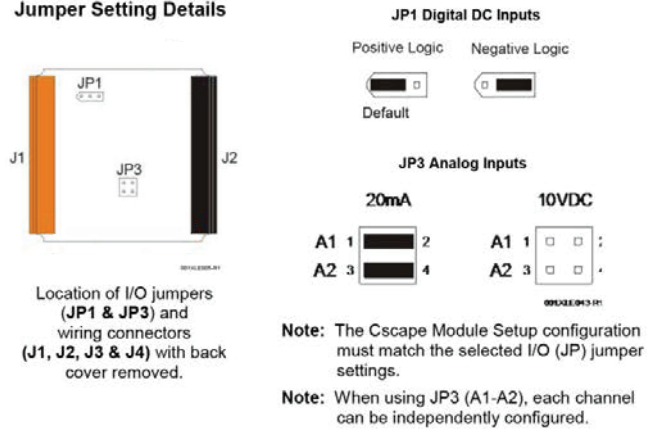
1.10 J2 (Black) Name

OV	Common
V+	V+
NC	No Connect
Q12	OUT 12
Q11	OUT 11
Q10	OUT 10
Q9	OUT 9
Q8	OUT 8
Q7	OUT 7
Q6	OUT 6
Q5	OUT 5
Q4	OUT 4
Q3	OUT 3
Q2	OUT2/PWM2
Q1	OUT1/PWM1

J2 Black
Positive Logic
Digital Out



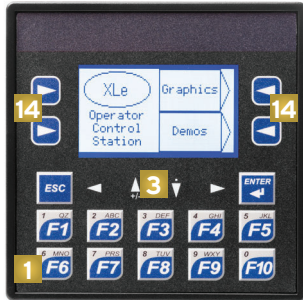
Jumper Setting Details



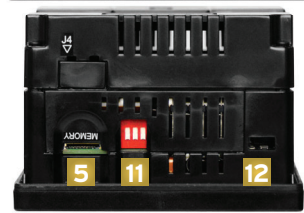
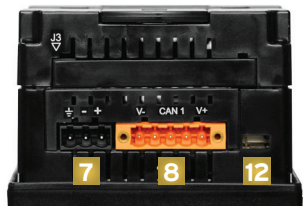
2 WIRING & CONNECTORS

3 COMMUNICATIONS

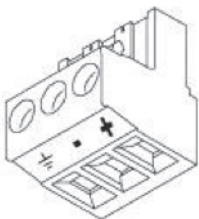
2.1 - Port Connectors



1. Function Keys
2. Touchscreen
3. Navigation Keys
4. USB Mini-B Port
5. High Capacity microSD Slot
6. RS232/RS485 Serial Ports (2)
7. Wide-Range DC Power
8. CAN Port
9. Ethernet LAN Port (optional)
10. Optional Built-In I/O
11. Configuration Switches
12. Mounting Clip Locations
13. DIN Rail Clip
14. Softkeys



2.2 - Power Wiring



Primary Power Port Pins

PIN	SIGNAL	DESCRIPTION
1	Ground	Frame Ground
2	DC-	Input Power Supply Ground
3	DC+	Input Power Supply Voltage

DC Input / Frame

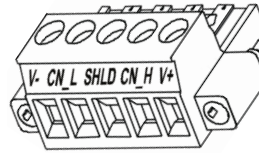
Solid/Stranded wire; 12-24 awg (2.5-0.2mm). Strip length - 0.28" (7mm).

Torque rating: 4.5 - 7 lb-in (0.50 - 0.78 N-m).

DC- is internally connected to I/O V-, but is isolated from CAN V-.

A Class 2 power supply must be used.

3.1 - CAN Communications

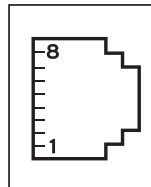


CAN
 Solid/Stranded wire; 12-24 awg (2.5-0.2mm). Strip length - 0.28" (7mm).
 Locking spring-clamp, two-terminators per conductor.
 Torque Rating: 4.5 lb-in (0.50 N-m). V+ pin is not internally connected, the SHLD pin is connected to Earth ground via a 1 MΩ resistor and 10 nF capacitor.

CAN Pin Assignments

PIN	SIGNAL	DESCRIPTION	DIRECTION
1	V-	CAN Ground - Black	-
2	CN L	CAN Data Low - Blue	IN/OUT
3	SHLD	Shield Ground - None	-
4	CN H	CAN Data High - White	IN/OUT
5	V+ (NC)	No Connect - Red	-

3.2 - Serial Communications

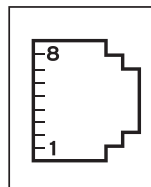


MJ1: RS-232 w/full handshaking or RS-485 half-duplex

RS-485 termination via switches; biasing via software

MJ1 PINS

PIN	SIGNAL	DIRECTION
8	TXD	OUT
7	RXD	IN
6	0V	GROUND
5	+5V at 60mA	OUT
4	RTS	OUT
3	CTS	IN
2	RX-/TX-	IN/OUT
1	RX+/TX+	IN/OUT



MJ2 SERIAL PORT

MJ2: RS-232 or RS-485 half or full-duplex, software selectable

RS-485 termination via switches; biasing via software

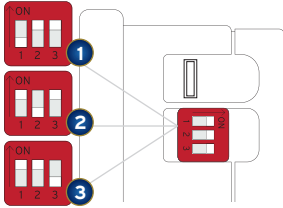
MJ2 PINS

PIN	SIGNAL	DIRECTION
8	232 TXD	OUT
7	232 RXD	IN
6	0 V	Ground
5	+5V@60mA	OUT
4	485 TX-	OUT
3	485 TX+	OUT
2	485 RX- or RX/TX-	IN or IN/OUT
1	485 RX+ or RX/TX+	IN or IN/OUT

communications continued on next page...

communications continued...

3.4 - Dip Switches

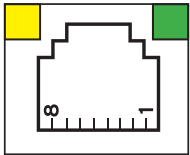


1.9 DIP SWITCHES

PIN	NAME	FUNCTION	DEFAULT
1	MJ1 RS-485 Termination	ON = Terminated	OFF
2	MJ2 RS-485 Termination	ON = Terminated	OFF
3	Bootload	Always Off	OFF

The DIP switches are used to provide a built-in termination to both the MJ1 port and MJ2 port if needed. The termination for these ports should only be used if this device is located at either end of the multidrop/daisy-chained RS-485 network.

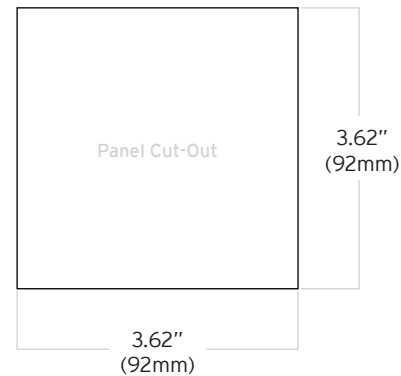
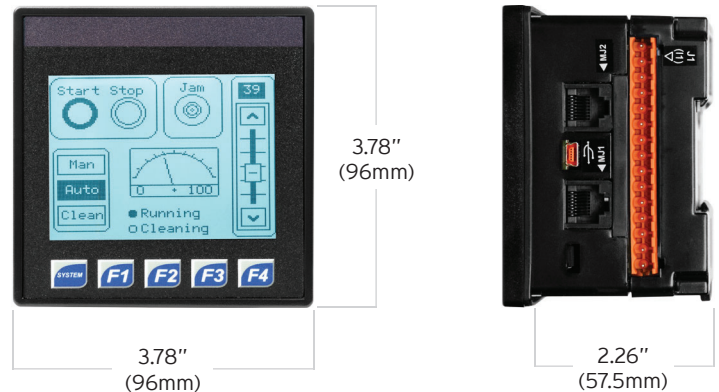
3.5 - Ethernet Communications



Green LED indicates link - when illuminated, data communication is available.

Yellow LED indicates activity - when flashing, data is in transmission.

5 INSTALLATION DIMENSIONS



4 BUILT-IN I/O

4.1 - 5. Built-in I/O (Model 2, 3, 4, 5 & 6)

All XLe and XLt models (except model 0) feature built-in I/O. The I/O is mapped into OCS Register space, in three separate areas - Digital/Analog I/O, High-Speed Counter I/O, and High-speed Output I/O. Digital/Analog I/O location is fixed starting at 1, but the High-speed Counter and High-speed Output references may be mapped to any open register location. For more details on using the High-Speed Counter and High-Speed Outputs, see the XLe/XLt OCS User's Manual (MAN0878).

FIXED ADDRESS	DIGITAL/ANALOG I/O FUNCTION	MODEL 2	MODEL 3	MODEL 4	MODEL 5	MODEL 6
%I	Digital Inputs	1-12	1-12	1-24	1-12	1-12
	Reserved	13-32	13-31	25-31	13-31	13-31
	ESCP Alarm	n/a	32	32	32	32
%Q	Digital Outputs	1-6	1-12	1-16	1-12	1-12
	Reserved	7-24	13-24	17-24	13-24	13-24
%AI	Analog Inputs	1-4	1-2	1-2	1-2	1-4; 33-38
	Reserved	5-12	3-12	3-12	3-12	n/a1-12
%AQ	Analog Outputs	n/a	n/a	n/a	9-12	9-12
	Reserved	n/a	1-8	1-8	1-8	

Reserved areas maintain backward compatibility with other XL Series OCS models

5.1 - Installation Procedure

The XLe/t utilizes a clip installation method to ensure a robust and watertight seal to the enclosure. Please follow the steps below for the proper installation and operation of the unit.

- Carefully locate an appropriate place to mount the XLe/t. Be sure to leave enough room at the top of the unit for insertion and removal of the microSD™ card.
- Carefully cut the host panel per the diagram on Page 1, creating a 92mm x 92mm +/-0.1mm opening into which the XLe/t may be installed. If the opening is too large, water may leak into the enclosure, potentially damaging the unit. If the opening is too small, the OCS may not fit through the hole without damage.
- Remove any burrs and or sharp edges and ensure the panel is not warped in the cutting process.
- Remove all Removable Terminals from the XLe/t. Insert the XLe/t through the panel cutout (from the front). The gasket must be between the host panel and the XLe/t.
- Install and tighten the four mounting clips (provided in the box) until the gasket forms a tight seal (max torque 0.8 to 1.13Nm, 7-10 lb-in).
- Reinstall the XLe/t I/O Removable Terminal Blocks. Connect communications cables to the serial port, USB ports, Ethernet port, and CAN port as required.

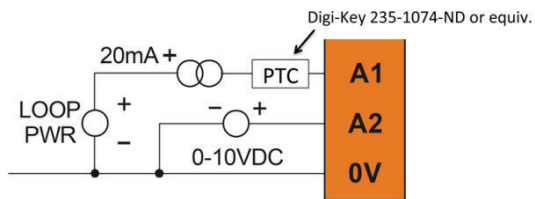
battery and safety warnings on next page...

6 BATTERY

The XLe/t uses a replaceable non-rechargeable 3V Lithium coin-cell battery (CR2450) to run the Real-Time Clock and to keep the retained register values. This battery is designed to maintain the clock and memory for 7-10 years. Please reference MAN0878 providing instructions on how to replace the battery.

7 ANALOG INPUT TRANZORB FAILURE

A common cause of Analog Input Tranzorb Failure on Analog Inputs Model 2, 3, 4, 5 & 6: If a 4- 20mA circuit is initially wired with loop power, but without a load, the Analog input could see 24Vdc. This is higher than the rating of the tranzorb. This can be solved by NOT connecting loop power prior to load connection, or by installing a low-cost PTC in series between the load and Analog input.



NOTE†: Refers to Model 2 - orange (pg. 1), Models 3 & 4 - J1 (pg. 2) and Model 5 - 20mA Analog In (pg. 3.)

8 SAFETY

8.1 - WARNINGS

1. To avoid the risk of electric shock or burns, always connect the safety (or earth) ground before making any other connections.
2. To reduce the risk of fire, electrical shock, or physical injury, it is strongly recommended to fuse the voltage measurement inputs. Be sure to locate fuses as close to the source as possible.
3. Replace fuse with the same type and rating to provide protection against risk of fire and shock hazards.
4. In the event of repeated failure, do NOT replace the fuse again as repeated failure indicates a defective condition that will NOT clear by replacing the fuse.
5. Only qualified electrical personnel familiar with the construction and operation of this equipment and the hazards involved should install, adjust, operate, or service this equipment. Read and understand this manual and other applicable manuals in their entirety before proceeding. Failure to observe this precaution could result in severe bodily injury or loss of life.

8.2 - FCC COMPLIANCE

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference
2. This device must accept any interference received, including interference that may cause undesired operation

8.3 - PRECAUTIONS

All applicable codes and standards need to be followed in the installation of this product. Adhere to the following safety precautions whenever any type of connection is made to the module:

1. Connect the safety (earth) ground on the power connector first before making any other connections.
2. When connecting to the electric circuits or pulse-initiating equipment, open their related breakers.
3. Do NOT make connection to live power lines.
4. Make connections to the module first; then connect to the circuit to be monitored.
5. Route power wires in a safe manner in accordance with good practice and local codes.
6. Wear proper personal protective equipment including safety glasses and insulated gloves when making connections to power circuits.
7. Ensure hands, shoes, and floor are dry before making any connection to a power line.
8. Make sure the unit is turned OFF before making connection to terminals.
9. Make sure all circuits are de-energized before making connections.
10. Before each use, inspect all cables for breaks or cracks in the insulation. Replace immediately if defective.
11. Use copper conductors in Field Wiring only, 60/75° C.

9 TECHNICAL SUPPORT

For assistance and manual updates, contact Technical Support at the following locations:

North America

(317) 916-4274
 www.hornerautomation.com
 techsppt@heapg.com

Europe

(+) 353-21-4321-266
 www.horner-apg.com
 techsppt@horner-apg.com

10 PART NUMBER BUILDER

EXAMPLE PART NUMBERS

GLOBAL MODEL NUMBERS

screen	ethernet	I/O
HE-X	1	
E (no touchscreen) T (touchscreen)	O (no ethernet) E (ethernet)	0 (model 0) 2 (model 2) 3 (model 3) 4 (model 4) 5 (model 5) 6 (model 6)

EUROPEAN MODEL NUMBERS

screen	ethernet	CAN option	I/O	overlay type
HEX		C		-
E22 (no touchscreen) T24 (touchscreen)	0 (no ethernet) 1 (ethernet)	0 (no CAN*) 1 (CsCAN) 2 (CANopen) 4 (DeviceNet) 5 (J1939)	00 (model 0) 12 (model 2) 13 (model 3) 14 (model 4) 15 (model 5) 16 (model 6)	00 (dark colour) 01 (light colour) 02 (blank) 03-99 (custom)

*No CAN is only available on XLe

A.3 VERIFY™ Product Information

1 Introduction

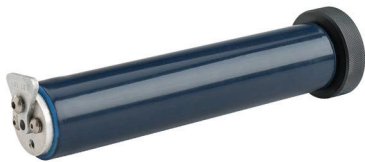
The VERIFY® All-In-One **STEAM** Reusable Test Pack is a multipurpose reusable test pack designed to challenge vacuum assisted steam sterilizers operating at 270°F for a 4 minute exposure. Each test pack can be used 200 times as a daily air removal test, routine microbial challenge pack, biological indicator test pack for load release or a chemical indicator test pack for release of loads without implantable devices.

The test pack has been validated for use with biological indicator models: Attest®¹ Rapid Read Biological Indicators, Attest® Super Rapid Read Biological Indicators and Smart-Read®² EZTest® Biological Indicators for Steam.

The VERIFY® Bowie Dick Indicator Strip is used in conjunction with the VERIFY All-In-One **STEAM** Reusable Test Pack to create the daily air removal test.

VERIFY® **STEAM** Integrating Indicators are included with each test pack purchased to provide compliance with ANSI/AAMI ST79 biological indicator test pack usage. The integrating indicator meets the performance specifications of a Type 5 integrating indicator as defined in ANSI/AAMI/ISO 11140-1.

2 Product



Use Application:

The VERIFY All-In-One **STEAM** Reusable Test Pack is a multipurpose reusable test pack designed to challenge vacuum assisted steam sterilizers operating at 270°F for a 4 minute exposure. Each test pack can be used 200 times as a daily air removal test, routine microbial challenge pack, biological indicator test pack for load release or a chemical indicator test pack for release of loads without implantable devices.

Device Description:

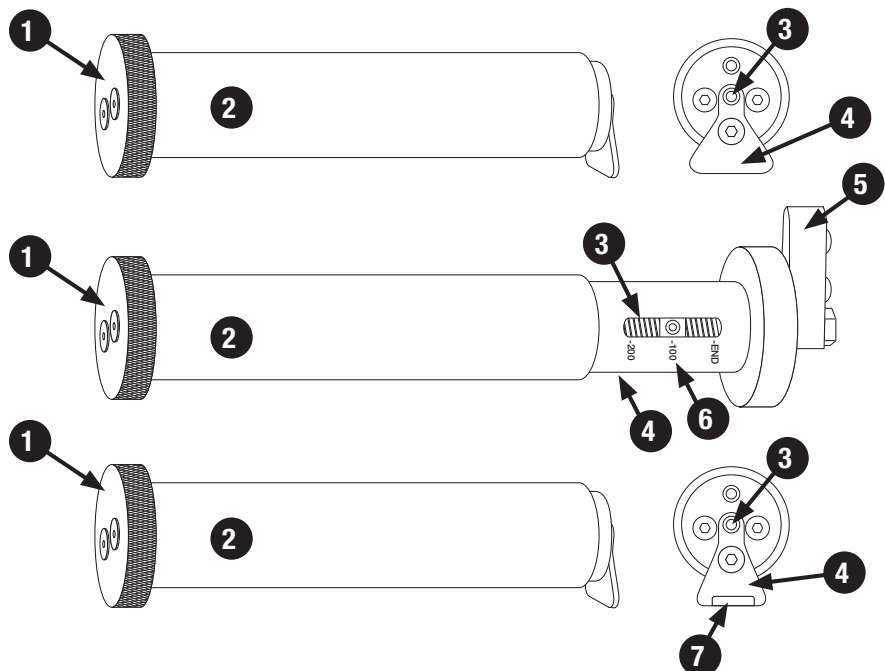
The VERIFY All-In-One **STEAM** Reusable Test Pack consists of a hollow tube-shaped process challenge device (PCD) for steam sterilization. A biological indicator, chemical indicator or both a biological and chemical indicator are placed within the hollow center of the metal tube. The PCD creates a challenge for air removal and steam penetration through a small orifice located at one end of the test pack. The orifice connects with an internal spiral lumen. The chamber housing the biological and chemical indicators is accessed through a removable cap located at the opposite end of the spiral lumen pathway.

1. Attest are registered trademarks of 3M Company

2. Smart-Read EZTest is the registered trademark of MesaLabs, Inc

The VERIFY Reusable test pack comprises three models: (1) Standard Test Pack, (2) Test Pack with Step Counter, (3) Test Pack with Tracker Tag.

COMPONENTS



1. Cap

2. Stainless Steel Tube with silicone coating

3. Access vent

4. Unique Identification Number

5. Counter Arm

6. Number Scale

7. Tracker Chip

VERIFY All-In-One **STEAM**
Reusable Test Pack (Standard)

VERIFY All-In-One **STEAM**
Reusable Test Pack with Step
Counter

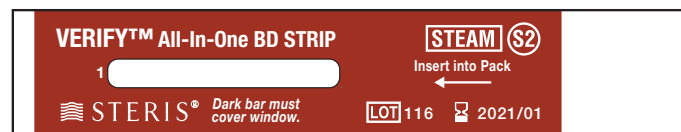
VERIFY All-In-One **STEAM**
Reusable Test Pack with Tracker
Tag

VERIFY Bowie Dick Indicator Strips:

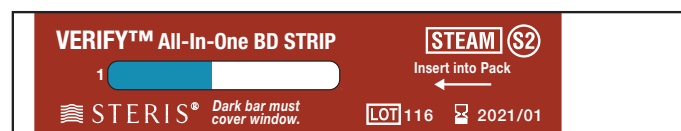


The reusable test packs use the VERIFY Bowie Dick Indicator Strips to challenge the air removal efficacy of prevacuum steam sterilizers operating at 270°F. Either the sterilizers preprogrammed Daily Air Removal Test Cycle (Bowie Dick Test Cycle) or a prevacuum cycle operating at 134°C/273°F with a 3.5 minute exposure and a 2 minute dry time may be used.

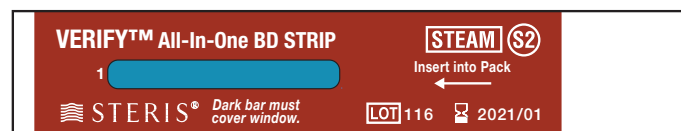
During the test cycle, the steam sensitive chemical located within the strip will wick across the viewing window. The dark color will completely fill the window if all air was removed from the reusable test pack and replaced by steam.



UNPROCESSED



PROCESSED REJECT



PROCESSED ACCEPT

DARK BAR MUST COMPLETELY COVER WINDOW

Biological Indicators:

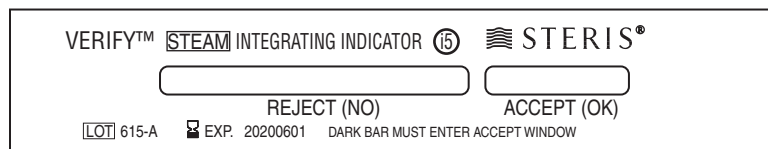
The reusable test packs have been validated with biological indicators commonly used to monitor steam sterilizers. Table 1 lists the validated biological indicators.

Table 1: Validated Biological Indicators.

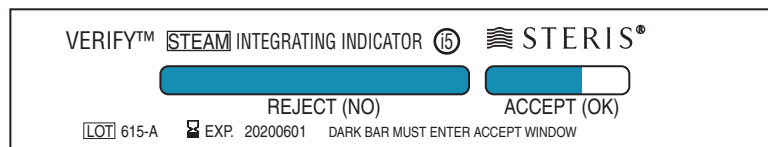
Biological Indicator	Product Number	Manufacturer
3M Attest Rapid Readout Biological Indicator	1292	3M Company
3m Attest Super Rapid Readout Biological Indicator	1492V	3M Company
Smart-Read EZTest Self Contained Biological Indicators for Steam	SEZS/5 and SEZS/6	MesaLabs, Inc.

VERIFY **STEAM** Integrating Indicators:

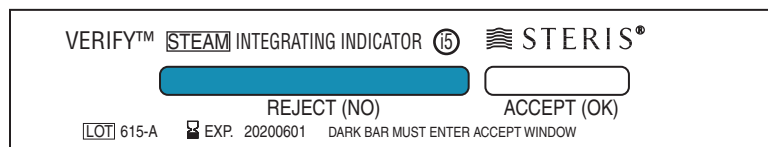
The VERIFY **STEAM** Integrating Indicator is used on its own or in conjunction with a biological indicator for routine monitoring and release of steam sterilized loads.



During the test cycle, the steam sensitive chemical located within the strip will wick across the “REJECT” viewing window and enter into the “ACCEPT” viewing window. Sufficient steam has entered the reusable test pack when any of the dark bar is visible within the “ACCEPT” Viewing window.



ACCEPT



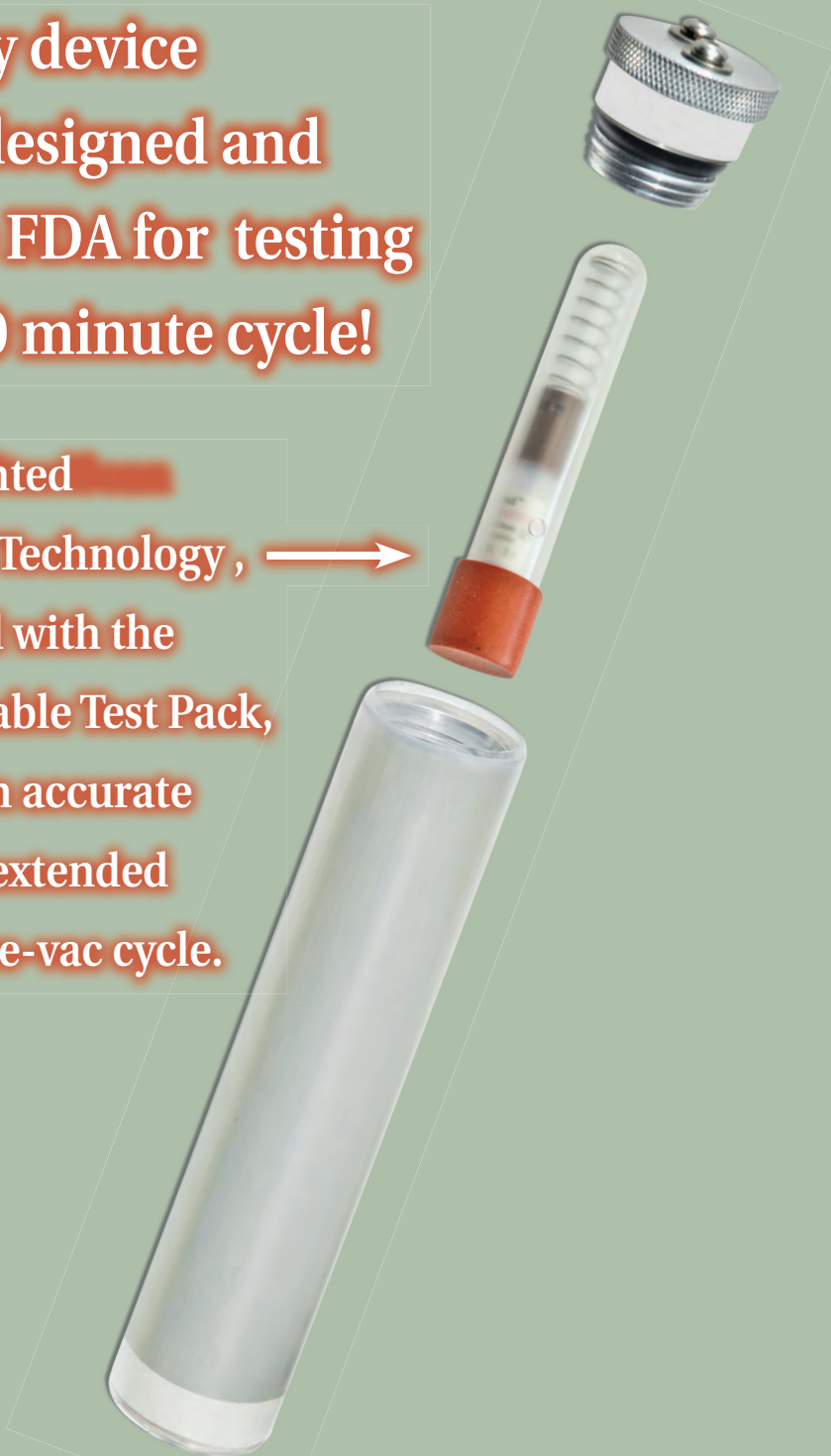
REJECT

VERIFY™ Extended Cycle Tube

Reusable Extended Cycle Test Pack for Biological Indicators
For 132° C (270° F) 10 Minute Pre-Vacuum Steam Sterilization Cycles

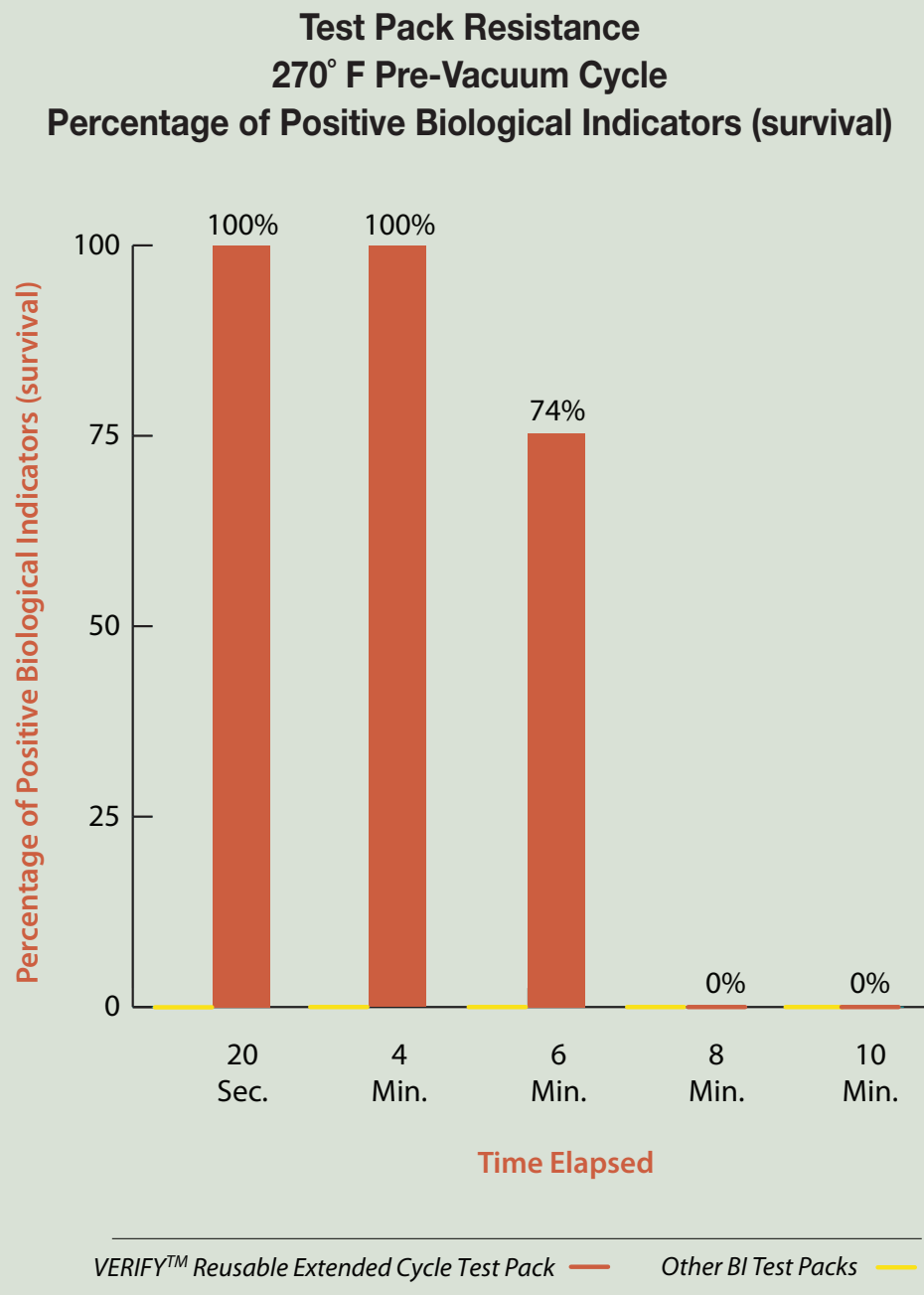
**The only device
specifically designed and
approved by the FDA for testing
an extended 10 minute cycle!**

**Patented
Plastic Sleeve Technology ,** →
**when used with the
SteriScan Reusable Test Pack,
provides an accurate
test of an extended
10 minute pre-vac cycle.**



U.S. Patent Nos. 7,740,802, 7,718,125 and 7,790,105. Other patents pending.

Challenges Extended Pre-Vac Cycles



A.4 WRS Pump Information

SHERTECH® Close-Coupled Turbine Pumps

Bronze and Cast Iron Models

Operation (Continued)

- On initial start-up, check power consumption to be sure motor is not overloaded.

NOTE: Never shut off discharge or restrict suction flow while unit is operating.

Maintenance

⚠ WARNING *Electric disconnect should only be done by a qualified electrician. Note: This pump can be challenging to work on. Only qualified repair technicians should be used. Improper repair and/or assembly can cause damage to pump/motor and also create an electric shock hazard.*

GENERAL

- Pump should be drained if subjected to freezing temperatures. A drain plug (Ref. No. 10) is provided on the pump casing.
- Clean the suction line strainer at regular intervals.
- Periodically clean dirt accumulations from open-type motors, especially in and around vent openings, preferably by vacuuming (avoids imbedding dirt in windings). Properly selected and installed electric motors are capable of operating for years with minimal maintenance.
- Pump motor (Ref. No. 1) is provided with sealed ball bearings. Normal relubrication of the bearings is not required.
- Periodically check that electrical connections are tight.
- Pump should be checked daily, weekly, monthly, etc. for proper operation. If anything has changed since unit was new, unit should be removed and repaired or replaced. Only qualified electricians or technicians should attempt to repair this unit. Improper repair and/or

assembly can cause an electrical shock hazard.

MECHANICAL SEAL

All Shertech pumps are furnished with a precision mechanical seal (Ref. No. 4). This seal is installed and checked at the factory and should require no adjustment at the time of the installation of the pump. Running the pump without water will result in rapid seal failure.

After the pump has been in service for a long period of time, or if the pump has seen severe service on abrasive materials, it may be necessary to replace this seal (the seal may leak). Leakage can be detected by a dripping or flow of liquid from the area around the motor shaft sleeve (Ref. No. 5).

⚠ CAUTION *Precision lapped faces on the mechanical seal are easily damaged. Handle your replacement seal carefully and read these instructions before attempting to replace the seal.*

DISASSEMBLY OF PUMP

After the plumbing has been removed from the intake and discharge ports, the pump can be readily disassembled.

- Remove the four 3/8" diameter bolts (Ref. No. 3) that attach to front cover (Ref. No. 9) of the body. Then remove the cover and o-ring gasket (Ref. No. 8).

⚠ CAUTION *Care should be taken not to pinch or "shave" the o-ring gasket (Ref. No. 8) between the adapter and the casing.*

- The impeller (Ref. No. 7) floats on the pump shaft sleeve (Ref. No. 5); therefore it can be readily removed (See Figure 4).
- Loosen set screw (Ref. No. 11) on pump shaft sleeve (Ref. No. 5). The pump shaft sleeve is threaded on the motor shaft. Turn the pump shaft sleeve counterclockwise to remove (See Figure 4).

NOTE: It will be necessary to hold the

motor shaft. A screwdriver slot or two flats for use with an open end 7/16" wrench are provided at the rear of the motor shaft (pry off cap for access). To prevent motor shaft from turning, either insert a larger screwdriver blade into the slot, or use a 7/16" wrench across the flats.

- The seal (part of Ref. No. 4a) will come off with the shaft sleeve (Ref. No. 5) (See Figure 4).

⚠ CAUTION *The precision carbon/ceramic faces on the mechanical seal are easily damaged. Handle your repair seal carefully. Do not touch the carbon/ceramic faces.*

- Remove the pump body (Ref. No. 2) and push out the seal seat (part of Ref. No. 4a) with a wooden dowel to remove the seal seat (See Figure 5).
- Clearance between the impeller (Ref. No. 7), the body (Ref. No. 2) and the cover (Ref. No. 9) is held to a minimum for high pressure performance. Therefore, any wear in these parts due to pumping abrasives, etc., would affect the pump performance. Replace parts when necessary.
- If it becomes necessary to replace the seal or seat, always replace them with a complete seal and seat assembly (Ref. No. 4a).
- Inspect the pump to see if the collar shown in Figure 7 is present. The mechanical seal requires the use of the collar to set the proper seal working height. If the collar (Ref. No. 4b) is not present, order item #17681 when ordering the replacement seal.

ASSEMBLY OF PUMP

IMPORTANT: Be sure that shaft shoulder does not damage carbon face.

- Thoroughly clean all surfaces of the seal seat cavity in adapter (Ref. No. 2).
- Using a clean cloth, wipe the shaft

Bronze and Cast Iron Models

Maintenance (Continued)

and shaft sleeve and make certain that they are perfectly clean.

3. Wet the rubber portion of the new seal seat (part of Ref. No. 4a) with a light coating of soapy water. While wearing clean gloves or using a clean light rag, press seal seat squarely into adapter recess. Use the cardboard washer (usually supplied with new seal) to place over the polished ceramic surface and use a piece of pipe or dowel rod to press in firmly but gently (See Figure 6). Avoid scratching the ceramic face, usually white.
4. Dispose of cardboard washer. Check again to see that ceramic surface is free of dirt and all other foreign particles and that it has not been scratched or damaged.
5. Assemble the collar (Ref. No. 4b), and seal (part of Ref. No. 4a) over the pump shaft sleeve (Ref. No. 5). If needed, a light coating of soapy water can be used on the inside of the seal bellows (part of Ref. No. 4 that fits onto the shaft) to facilitate for easier installation (see Figure 7).
6. Screw the pump shaft sleeve (Ref. No. 5) onto the motor shaft and turn clockwise until it bottoms. This location provides the proper seal tension for good surface contact between the seal and seat. If the key is assembled in the pump shaft before the shaft is threaded on, it will provide a better grip for tightening. Tighten setscrew (Ref. No. 11) on sleeve (See Figure 7).

NOTE: A short "run-in" period may be necessary to provide completely leak-proof seal operation.

NOTE: It will be necessary to remove plug in motor end cap to expose slot. If removed, be sure to reinstall plug AFTER pump is completely assembled.

7. Assemble the impeller (Ref. No. 7) over the pump shaft sleeve (Ref. No. 5). Make sure the impeller floats freely (see Figure 7).
8. Assemble the o-ring gasket (Ref. No. 8) and attach the cover (Ref. No. 9) with the (4) 3/8" diameter screws (Ref. No. 3). Torque to 15 to 20 ft-lbs.. (See Figure 7).
9. Before and after the plumbing is attached to the pump, make sure the pump turns freely. Rotate the pump by inserting a screwdriver into the back end of the motor and turning the motor shaft.

⚠ CAUTION *Seal will produce some minor drag when spinning motor shaft, but rubbing anywhere else must be eliminated! Otherwise, damage to pump and/or motor may occur.*

SHERTECH® Close-Coupled Turbine Pumps

Bronze and Cast Iron Models

Seal Assembly Removal and Installation (Figures 4 thru 7)

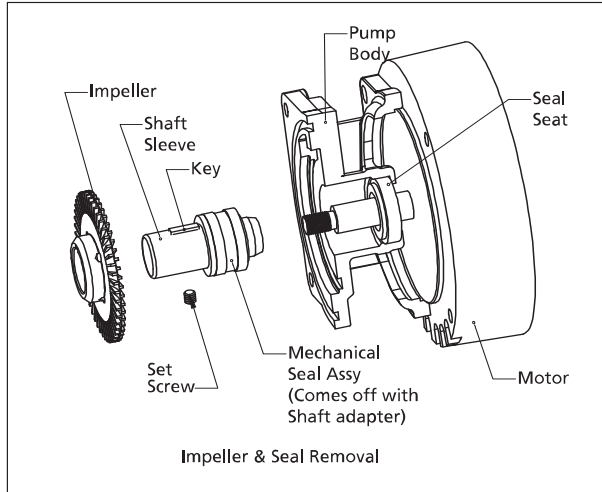


Figure 4 - Impeller, Sleeve and Seal Assembly Removal

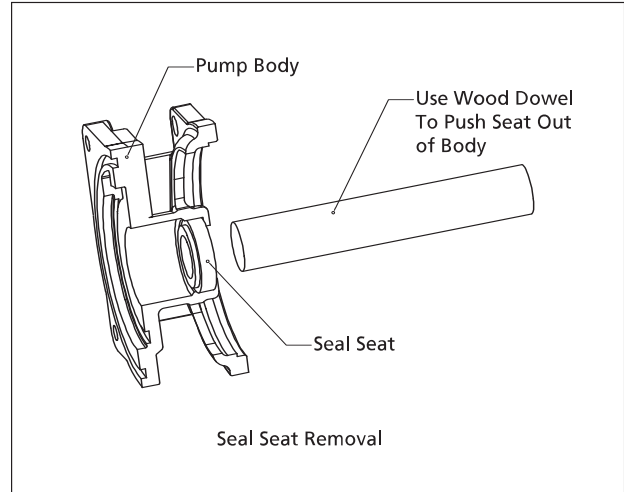


Figure 5 - Seal Seat Removal

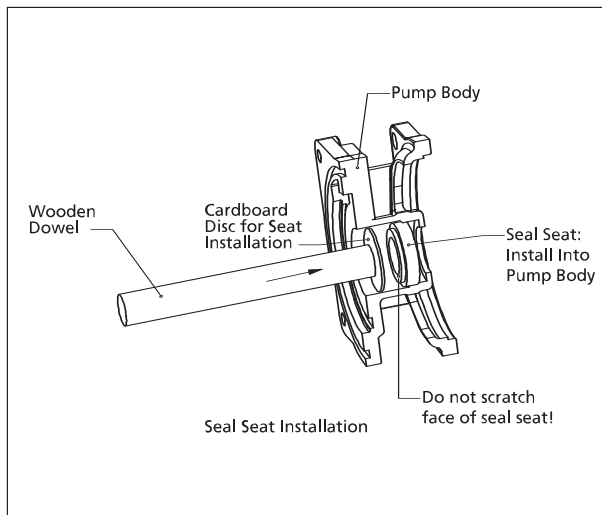


Figure 6 - Seal Seat Installation

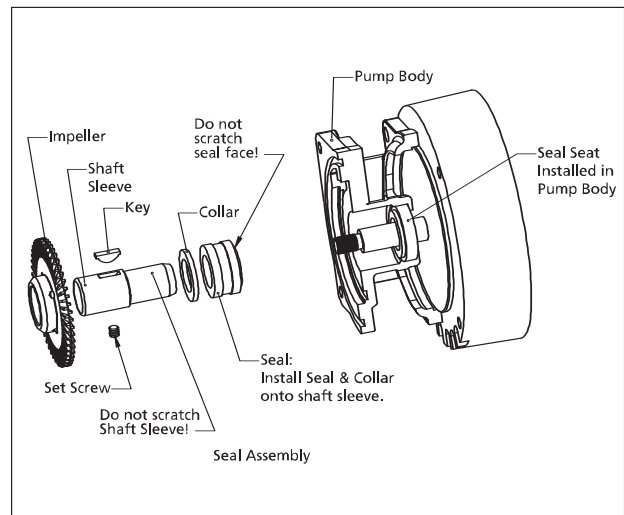


Figure 7 - Seal, Collar, Sleeve and Impeller Installation

(S/N's AFS-0001 through AFS-0236)

Shertech Operating Instructions, Performance,
Specifications and Parts Manual

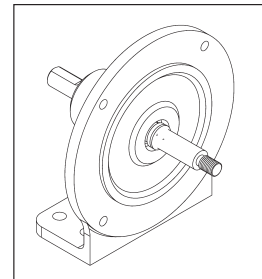
Contact a Shertech Distributor

Distributors can be found at www.shertech.com or www.hyproindustrial.com

(The factory only sells pumps and parts to distributors.)

Please provide following information:

- Model number
- Serial number (if any)
- Part description and number
as shown in parts list



Optional Pedestal Base

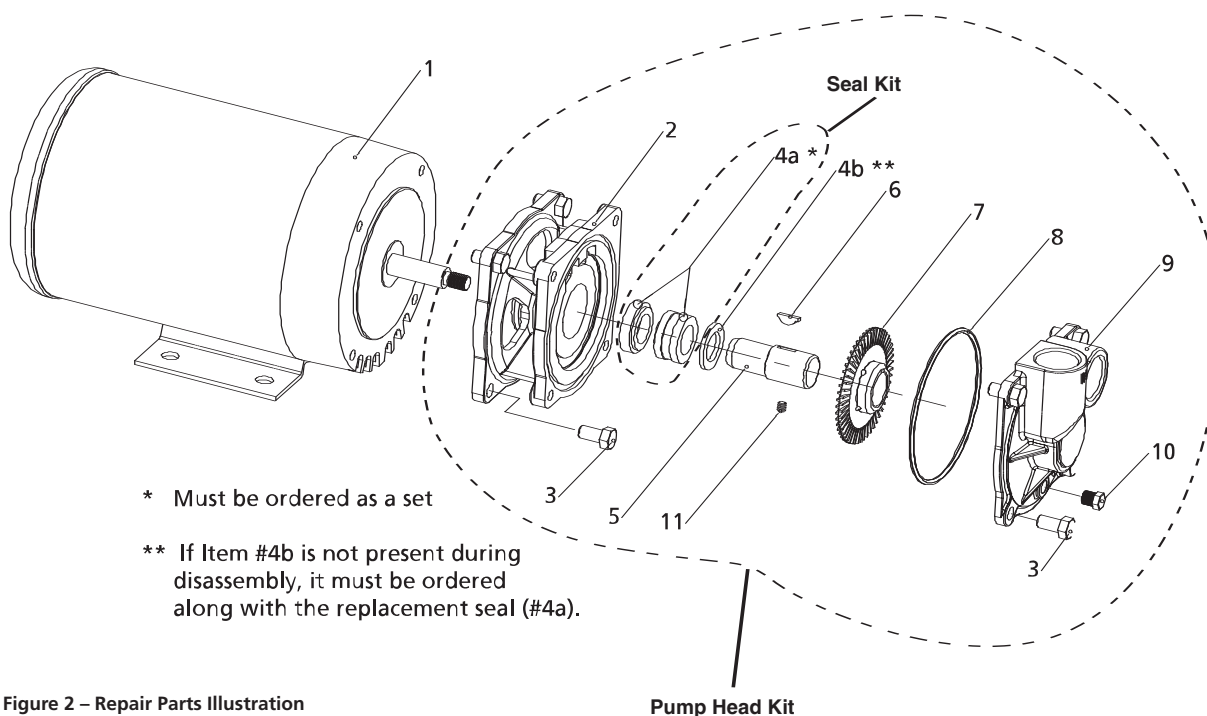


Figure 2 – Repair Parts Illustration

Pump Head Kit

T31 SERIES

3. Operation

CLOSE COUPLED PUMPS
FLEXIBLE COUPLED PUMPS

- A. Rotation
- B. Inlet and Outlet Locations
- C. Foreign Material
- D. Electrical
- E. Adjustments
- F. Cooling Water
- G. Priming
- H. Starting
- I. Stopping

3A Rotation

The standard direction of rotation of the pump is right handed, or clockwise when looking at the motor end of the pump. A rotation arrow, refer to Figure 3-1, is located on the pump to indicate the correct direction of rotation.

Operating the pump in reverse will cause substantial performance variations and can damage the pump.

Always confirm correct motor rotation prior to connection of the coupling. If this is not possible, or a final rotation check is being performed:

1. Jog the motor briefly.
2. Observe rotation as the unit comes to a stop.
3. Rotation should be in the direction of the arrow.

If the motor operates in the wrong direction:

1. Interchange any two leads on a three phase motor.
2. On a single phase motor, change the leads as indicated on the connection box cover. Some single phase motors may not be reversible.

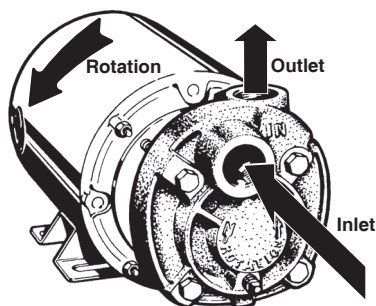


Figure 3-1

3B Inlet and Outlet Locations (Refer to Figure 3-1)

The pump inlet is located on the end farthest from the motor. The discharge or "outlet" can be on the top, side, or bottom depending on the model and construction of the pump. Normal discharge position is on top.

3C Foreign Material

All regenerative turbine pumps have close running clearances in order to maintain efficiency. Take extra precautions to insure that no foreign material larger than 25 microns or .001 inches is allowed to pass through the pump. Even particles of this size can damage the pump if allowed to continue. Regenerative turbine pumps are not designed for slurries.

Large particles, weld spatter, and other material found in new piping systems will bend the impeller vanes and can sometimes lock up the pump. If a new pump does not operate properly, the first thing to check for is damage from foreign material.

3D Electrical

It is important to be aware of and follow the appropriate local and national electrical codes. Do not make wiring alterations that can affect motor rotation without reconfirming correct rotation. Select starter heaters and wiring for the maximum current the motor can use at full service factor loads. Regenerative turbine pumps will typically use extra power for a period until they run in. This can take three to four weeks depending on the duty cycle. During this period, impellers are finding their hydraulically balanced position.

3E Adjustments

No adjustments are required or advisable on new pumps. Because of the close fits in regenerative turbine pumps, it is not uncommon for the pump to be difficult to turn over by hand after they have been allowed to dry out inside. New pumps from the factory are tested using rust inhibitors to preclude this possibility. On site system flushing may remove these inhibitors and subject the pump to the risk of lock up, if it is allowed to dry out. In this case, do the following:

1. Fill the pump with fluid.
2. Loosen the thrubolts exactly one turn.

3. Jog the pump momentarily using the on/off buttons if so equipped.
4. This should "break" the impeller loose without damage, unless foreign material has entered the pump.
5. If possible, spin the pump (or operate with minimal or zero discharge pressure) while the thrubolts are retightened exactly one turn.

This will flush residue from the close fitting impeller surfaces.

Because of the large areas of close fitting surfaces inside these pumps, it takes only microscopic residue to produce resistance to rotation. Once loosened, this material is quickly dispersed and the impellers will find their hydraulic center. If these procedures have been followed, no damage will have resulted from "breaking loose" the impeller.

3F Cooling Water

When the pump is used to pump hot fluids, consideration should be given to cooling the seals and/or selecting materials that will give satisfactory seal life. The actual temperature at the seal faces, the most critical area, will always exceed the surrounding fluid temperature. If seal flushing lines have not been installed, heat can build up in the seal faces to a degree that may destroy the fluid film necessary to prevent rapid wear. In some cases it is necessary to cool the seal flushing fluid. Refer to the seal manufacturers charts for guidance or to selection data in the MTH catalog anytime fluids can reach or exceed their boiling point.

3G Priming

Pumps should not be operated unless they are completely filled with liquid. Damage to parts of the pump that depend on liquid for their lubrication can occur. Impellers can seize quickly when a pump is run dry. Without lubrication, seal faces can be damaged from heat buildup.

Pumps can be easily primed with a vacuum pump. An ejector or liquid ring vacuum pump is recommended for this purpose because they are not damaged if liquid enters them.

(S/N's after AFS-0236)

Connect the vacuum line to the discharge side of the pump, either in the discharge opening or the drain tap. A foot valve is not necessary when this kind of device is used.

When a vacuum pump is not practical, a foot valve in the suction inlet can be used to prevent liquid from running out. The pump and suction line can then be filled completely from an outside source. A vent opening will be necessary during filling to let air escape. A tight foot valve will keep the pump constantly primed so that automatic operation is possible. The valve should be inspected regularly to see that it does not develop leaks which would allow the pump to run dry.

Optional self-priming casings are available for MTH pumps allowing priming when a vacuum pump or foot valve is not practical. Refer to specific literature for details.

There are four components to the self primer:

1. A check valve - necessary to maintain a vacuum in the suction line as surging occurs in the pump.
2. An air eliminator - used on the discharge side of the pump to separate air from liquid so the liquid can be used again as air is carried through the pump.
3. A recirculating line - carries liquid from the air eliminator to the suction.
4. A fluid chamber - used on the inlet side to provide a supply of fluid to speed up priming.

Small suction lines are desirable to minimize priming time.

Using the self priming casing, it is only necessary to:

1. Open the plugs in both the inlet and discharge chambers.
2. Pour fluid in one until both are full.
3. Tighten both plugs.
4. Turn on the pump.

T31 SERIES

4. Maintenance

CLOSE COUPLED PUMPS

- A. Seals
- B. Cooling Water
- C. Lubrication

4A Seals

Mechanical seals are used in MTH Pumps to eliminate the maintenance that is normally associated with packing

Priming time depends on lift, volume of air in the suction line, and the size of the regenerative turbine pump used. If priming time is long and the pump becomes warm, refill the priming chambers with fresh liquid. Most turbine pumps will pump twenty-six to twenty-eight inches of mercury vacuum with cold water in the pump, but have very little capacity and therefore are not practical at lifts over twenty-two feet.

The best way to prime a pump and keep it primed is to use a flooded suction. While this is not always practical, it does provide a number of advantages. The likelihood of pump damage from dry running is eliminated. Suction lines may be large, reducing line losses and minimizing the potential of cavitation damage. There are no check valves or priming devices to fail or require maintenance. Whenever possible, design pumping systems with flooded suction.

3H Starting

Before starting a pump for the first time, be sure that all the preceding operations have been carried out. Proper rotation, priming, and a free turning pump are most important.

1. Start the pump with the minimum possible line restriction.
2. Open discharge valves before pressing the starter.
3. Start the pump and let the system clear of air.
4. Listen for foreign material being carried through the pump.
5. Slowly close necessary valves or otherwise place the pump into service.
6. Listen for indications of undue load or other sounds indicating problems.
7. Use a clip-on ammeter to check for a steady load after approximately fifteen minutes of operation.

3I Stopping

It is best to stop the pump with the least discharge head possible both for minimizing strain on components and to be in low power mode in anticipation of

restarting. If the pump will be down for more than a few weeks it is advisable to drain it. Follow the instructions for long term storage, Section 1, 1B Storage. After any prolonged stoppage, turn the pump over by hand before restarting, to be sure it is free.

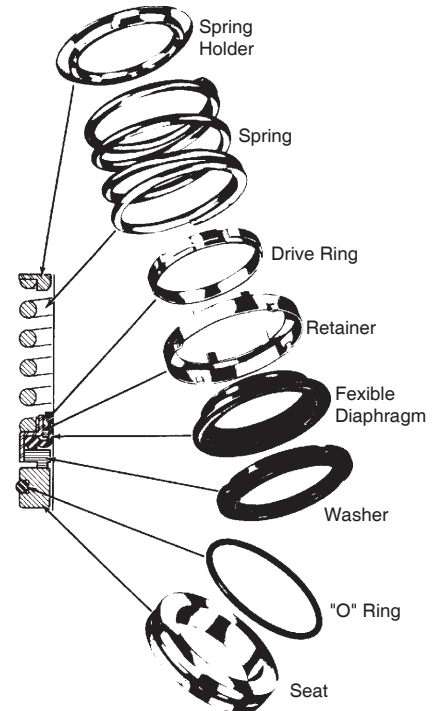


Figure 4-1

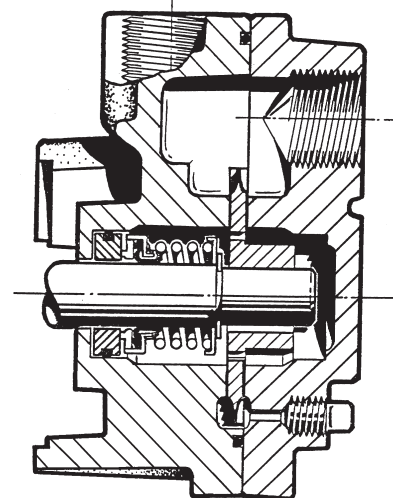


Figure 4-2 Standard Seal Construction

boxes. This does not, however, mean they can totally be ignored. Check a new installation for seal leakage.

Maintenance of seals consists primarily of periodic observation, looking for the first signs of failure. An occasional drip that continues to worsen is an indication that the seal has failed and must be replaced. Follow the appropriate disas-

sembly/assembly instructions. Always shut down a pump with failed seals as soon as possible. Leaky seals are usually followed by bearing failures and then possible pump damage as rotating parts become mis-aligned.

4B Cooling Water

If a heat exchanger is used to supply cooling water for the seals, check the

(S/N's after AFS-0236)

system periodically in the same way as 4B. As an additional system check, measure the temperature as it leaves the heat exchanger. This can be done with an external contact thermometer or by adding an appropriate fitting and internal thermometer. Cooling water should be kept below 200°F. External cooling water sources should be checked for temperature and pressure. Line pressure at the seal chamber fitting

must exceed that in the seal chamber by at least 5 psi. Refer to the specific instruction sheets for further cooling system information.

4C Lubrication

Sealed ball bearings are standard in all MTH pumps. The maximum continuous operating temperature for bearings is 250°F. While it is not advisable to routinely disassemble sealed bearings,

it is possible to remove the seals during disassembly and determine their condition. Use new bearings for reassembly. While the pump is in service, listen for unusual sounds or changes in bearing noise. A screwdriver held between the bearing housing and your ear while the pump is rotated by hand is sometimes helpful if there is too much ambient noise when the system is operating.

T31 SERIES

5. Service

PUMP ENDS

- A. Preliminary
- B. Disassembly
- C. Inspection of Components
- D. Reassembly
- E. Testing and Final Adjustments

5A Preliminary

Before attempting any service on the pump or motor, disconnect the electrical power to the pump motor. If the pump and motor are to be removed as a unit, note the wiring configuration. Use colored or numbered tape to mark the wire connections of the motor and power source, for reconnection. If the pump is being used to pump hot liquid, let the pump and liquid cool before starting disassembly.

1. Disconnect the inlet and outlet piping before unbolting the pump and motor. If the pipes are corroded, use penetrating oil on the threads to aid in removal.
2. Unbolt the motor from the base and remove the unit. All work on the unit should be performed on an elevated workbench whenever possible.

5B Disassembly

The following tools and equipment are needed for disassembly of T31 Series Pumps:

1. Soft plastic or wooden mallet.
2. Small ball peen hammer.
3. 10mm wrench or socket
4. Snap ring pliers.
5. Penetrating oil.
6. 11/16" wood dowel (Approx. 6" long.)
7. Thin blade screwdriver.

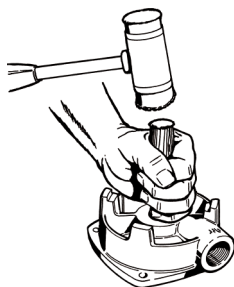


Figure 5-1

8. Cealube G or similar glycol base lubricant. (DO NOT use petroleum products.)

To disassemble the pump:

Refer to Figure 5-2 for reference to the numbered parts in the procedures below.

1. Remove all liquid from the pump. Air blown through the pump will remove the water quickly.
2. Remove the four (4) M6-1 X 80mm bolts (#19) from the cover (#2).
3. Remove the cover. In some cases light tapping with a plastic or wooden mallet on the outside diameter of the cover may be required to loosen it from the motor bracket. Care should be taken if a screwdriver is needed to pry between the cover and motor bracket. Damage to the "O" ring (#7) and/or impeller (#11) can result.
4. Remove the impeller. This is easily done by setting the motor on end. The impeller is a slip fit and under normal conditions, can be removed by hand or by gently tapping on the end of the shaft with a mallet. Striking the shaft too hard could damage the seat, rotating element, or the motor. After removing the impeller, the impeller key (#23) needs to be removed from the shaft keyway.
5. Remove the snap ring (#4) from the shaft; note the spring that is held in place by the snap ring. Remove the spring from the shaft.
6. To remove the rotating element (#12), gently slide the motor bracket (#1) forward on the shaft to move the rotating element high enough to be removed by hand. Using tools on the rotating element may damage the rotating element or the seat. Take precautions to keep the rotating element clean if it is to be reused.
7. Next remove the motor bracket.

8. To remove the seat (#125). Refer to Figure 5-1. Place the motor bracket face down on a clean flat surface. Look into the opening in the center of the motor bracket, and you will see a portion of the seat. Insert the 11/16" dowel and, very gently, tap the seat until it drops out. Care must be taken with the seat. It is often a brittle material and is prone to breakage. **It is recommended that a new replacement seat be installed during reassembly.**

5C Inspection of Components

Thoroughly clean all parts. All components should be examined for wear and corrosion. Replace any parts that show visible wear. If the pump was not producing sufficient pressure or capacity, the clearances between the rings and impeller probably exceed the maximum allowable clearance. At minimum the impeller should be replaced in this case. If the total side running clearance for an impeller exceeds .007", it is unlikely that pump performance will reach that of a new pump except at lower discharge pressures.

The "O" rings and other elastomeric components should be replaced if they have been deformed or cut.

If seal components must be reused, carefully inspect for microscopic cracks and nicks. Scratches that might be ignored elsewhere can produce leakage if they are on seal carbons and seat wearing surfaces.

Cleanliness is imperative when working with mechanical seals. Almost unnoticeable particles between seal faces can be, and often are, the cause of early seal failures.

Check the impeller; it is designed to float. It should move easily on the shaft. As long as it can be moved on the shaft by hand, it is loose enough. If the impeller can be rocked or wobbled, it is too loose and must be replaced.

Check the shaft for galling, pitting, and corrosion. If the shaft is corroded where the seal comes in contact with the shaft,

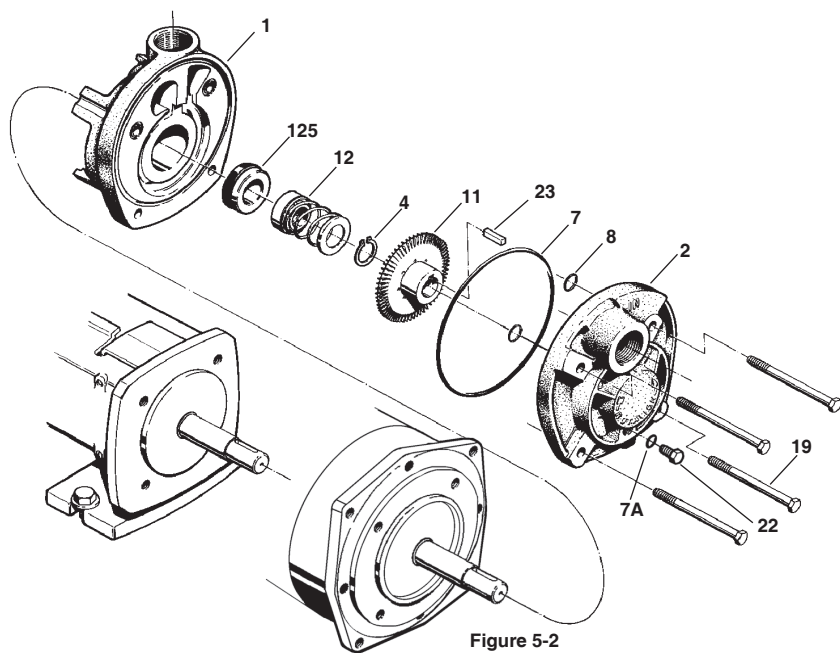


Figure 5-2

the motor or bearing pedestal shaft must be replaced. Surface corrosion must be removed so that seals can slide freely during assembly. The shaft diameter should be no smaller than .002" below the nominal fractional seal sizes. Remove any nicks or burrs which may have occurred during disassembly. Re-clean parts as necessary.

5D Reassembly

All parts should be visually inspected and cleaned or replaced as outlined in 5C above.

- The seal seat (#125) must be installed in the motor bracket (#1) before the bracket is installed on the motor. To install the seat:
 - Place the motor bracket face up on a flat surface.
 - Apply a coating of compatible lubricant to the elastomer portion of the seat to aid with installation.
 - Carefully press the seat, smooth side up, into the seat cavity of the motor bracket. Thumb pressure is usually sufficient to install the seat.
- Install the motor bracket. This is best done with the motor standing on end. Make sure that both the "C"-face of the motor and the feet of the motor bracket are clean. Slide the motor bracket over the shaft onto the motor.
- Install the rotating element (#12). Lubricate I.D. of the rotating element. Place the rotating element on the shaft with the carbon end towards the seat. Place the spring over the shaft, with the backing plate up and compress the spring to locate the rotating

element against the seat. If this fails to seat the rotating element gently push the rotating element down with a thin blade screwdriver being careful not to damage the seat or the rotating element.

- Compress and hold the seal spring slightly below the snap ring groove and install the snap ring (#4). Make sure the snap ring is locked in the groove.
- Install the impeller key (#23) into the shaft keyway.
- The impeller is a slip fit and should slide on firmly but easily until it stops against the impeller wearing surface. Force should not be required or used to install the impeller in the correct position. The impeller hub should be facing out away from the motor bracket. Refer to Figure 5-2.
- Next, rotate the impeller by hand, the impeller should move freely.
- Place the large "O" ring (#7) into the outside "O" ring groove in the motor bracket. Place the two (2) smaller "O" rings (#8) into the smaller "O" ring grooves.
- Place the cover (#2) over the motor bracket and install the four (4) M6-1 X 80mm bolts (#19). Tighten the bolts systematically, alternating diagonally across the cover. DO NOT exceed 7-11 ft. lbs. of torque or damage to the motor "C"-face may occur.

5E Testing and Final Adjustment

The pump is now ready for installation. Final adjustments will be made with the pump in operation.

T31 CLOSE COUPLED PUMP

NAME/DESCRIPTION	PART NO.	QTY.
Motor Bracket	1	1
Cover	2	1
"O" Ring/Casing	7	1
"O" Ring/Drain Plug	7A	1
"O" Ring/Thru Bolt	8	2
Snap Ring	4	1
Impeller	11	1
Seal Rotating Element	12	1
Seal Stationary Seat	125	1
Thru Bolt	19	4
Pipe Plug	22	1
Key/Impeller Drive	23	1

- Connect all piping and fill the pump with fluid.
- Reconnect the electrical connections, referring to the colored or numbered tape used to mark the wires.
- Make sure all valves are opened, and fluid will flow through the system.
- Start the pump and make the final adjustments to the M6 bolts holding the cover on. These nuts and bolts must be torqued to about 7-11 ft. lbs. to obtain proper performance.
- Check for leaks on pump and piping. Special attention should be given to the seal area at the rear opening in the motor bracket.
- Under pressure, the impeller will find its "hydraulic" balance.
- Using an amprobe or similar device, check for motor overload.
- While the impeller is seating, it is common to experience some variance in readings. After a run-in period the readings should level off.

This completes the adjustment and testing phase. The pump is ready for service.

BEARING PEDESTALS

- Preliminary
- Disassembly
- Inspection of Components
- Reassembly
- Testing and Final Adjustments

5A Preliminary P2

- Disconnect the inlet and outlet piping before unbolting the pump. If the pipes are corroded, use penetrating oil on the threads to aid in removal.
- Unbolt the pump from the base and remove. Disassembly instructions for the pump are found in Section 5, T31 PUMP ENDS. All work on the unit should be performed on an elevated workbench whenever possible.

The disassembly and reassembly procedures are broken into two sections covering the following units :

(S/N's after AFS-0236)

5B — Disassembly of the P2 Unit.
5D — Reassembly of the P2 Unit.

An exploded view of the unit, Figure 5-3 is provided for referencing the numbers in the following procedures, i.e. flinger (#21).

5B Disassembly

The following tools and equipment are needed for disassembly of the P2 unit:

Tools:

1. Soft plastic or wooden mallet.
2. Arbor press or vise.
3. 3/4" X 6" piece of water pipe.
4. Internal snap ring plier.
5. Penetrating oil.

When installing or removing bearings from the shaft, the use of an arbor press is strongly recommended.

To disassemble the pedestal:

Refer to Figure 5-3 for reference to the numbered parts in the procedures.

1. Remove the flinger (#21) located in the pump end of the bearing pedestal (#3).

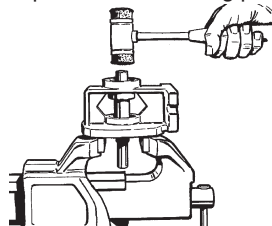


Figure 5-4

2. Using a snap ring plier, remove snap ring (#4).
3. Open the jaws of the vice approximately 2-1/4".
4. Place the pedestal, pump side down, on the jaws. Refer to Figure 5-4.
5. Using a plastic or wooden mallet, gently tap on the end of the shaft until it slides out of the frame. Both bearings should come out with the shaft. Do not use a metal hammer, severe damage to the shaft will occur.
6. Using the arbor press, remove the two (2) bearings from the shaft. Refer to Figure 5-5. If the inner race is well

P2 BEARING PEDESTAL

NAME/DESCRIPTION	PART NO.	QTY.
Bearing Pedestal	3	1
Snap Ring/ Bearing Retaining	4	1
Shaft	17	1
Flinger	21	1
Key Coupling	23	1
Ball Bearing/Inboard	24	1
Ball Bearing/Outboard	24A	1
Coupling Guard/Halves	30	2
Capscrew	33	4

supported during this operation, no damage will be done to the bearings.

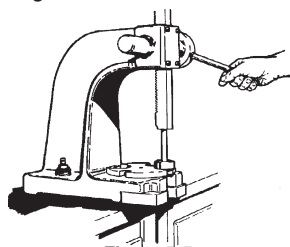


Figure 5-5

If an arbor press is not available, a bench vise may be substituted using the following instructions.

1. Remove the pedestal and close the jaws to approximately 1-1/8".
2. Place the shaft with either bearing resting on top of the jaws and gently tap on the end of the shaft until the bearing is removed. Refer to Figure 5-6.

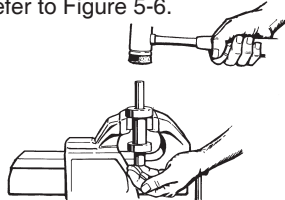


Figure 5-6

3. Repeat step 2 to remove the other bearing. Good support used on the inner races will prevent bearing damage.

5C Inspection of Components

Thoroughly clean all parts. All components should be examined for wear and corrosion. Replace any parts showing visible wear.

Check to be certain that a press fit still exists between the shaft and the bearings. New bearings, or at least cleaned and re-greased bearings, are recommended.

Check the shaft for galling, pitting, and corrosion. Surface corrosion on the pump portion of the shaft must be removed so the seals will slide freely during assembly. The shaft diameter

should be no smaller than .002" below the nominal fractional seal sizes. Remove any nicks or burrs which may have occurred during disassembly. Re-clean parts as necessary.

5D Reassembly

All parts should be visually inspected and cleaned or replaced as outlined in 5C above. It is recommended that the bearings be replaced anytime the bearing pedestal is disassembled for service.

1. Using an arbor press, install the bearings on the shaft prior to installing the shaft into the pedestal. A steel "donut" with the proper inside diameter and outside diameter, Refer to Chart 1, should be used between the arbor face plate and the lower bearing to insure proper installation and to prevent bearing damage. The bearings must seat against the shoulder for proper alignment. Refer to Figure 5-7. *Also refer to Alternate bearing installation procedures.

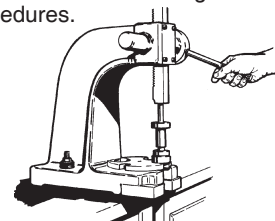


Figure 5-7

CHART 1	P2
Inside Diameter	1"
Outside Diameter	2"

2. Place the pedestal, pump mounting surface up, in a vise or suitable fixture and insert the bearing assembly. It should be possible to install the shaft assembly with firm thumb pressure. Refer to Figure 5-8. If more force is required, the butt end of a hammer handle or plastic mallet may be helpful. The shaft assembly should never be forced or driven in.

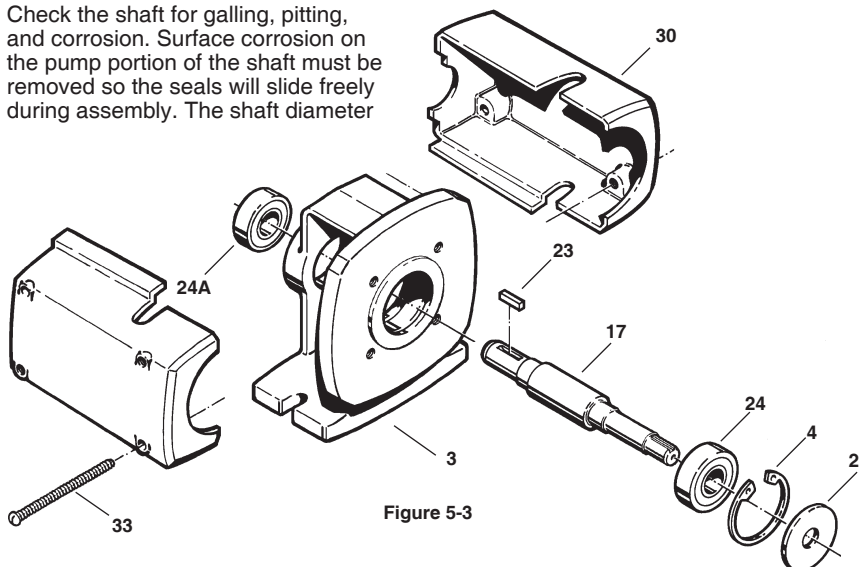


Figure 5-3

(S/N's after AFS-0236)

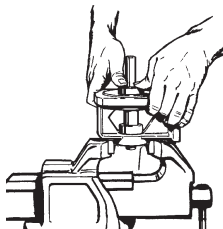


Figure 5-8

3. Install the snap ring (#4) in the pump end of the pedestal. Be sure the snap ring is seated properly in the groove. The beveled edge of the ring should face away from the bearing.

4. Install the flinger over the snap ring. The bearing pedestal is now ready for pump and motor installation.

***Alternate bearing installation procedures.**

If an arbor press is not available, the bearings may be installed on the shaft using the following procedure:

This procedure is not recommended and should only be used in an emergency situation.

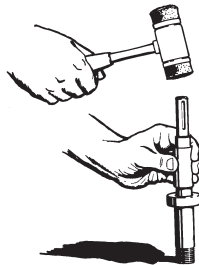


Figure 5-9

1. Stand a piece of 3/4" pipe, with the threads cut off, on a workbench or similar flat surface, with the bearing placed on the correct shaft end.

2. Insert the shaft into the pipe so the bearing is between the pipe and the shoulder of the shaft. Refer to Figure 5-9.

3. Using extreme caution, gently tap on the end of the shaft until the bearing rests against the shoulder. Never attempt to install the bearings by striking the outer race.

4. Repeat step 3 for the other bearing.

5E Testing and Final Adjustments

1. Check to be sure that the rotating assembly turns freely. Turn the shaft by hand. If it is tight or rough spots are encountered, it is likely that at least one of the bearings was damaged during disassembly/assembly operations and will have to be replaced.

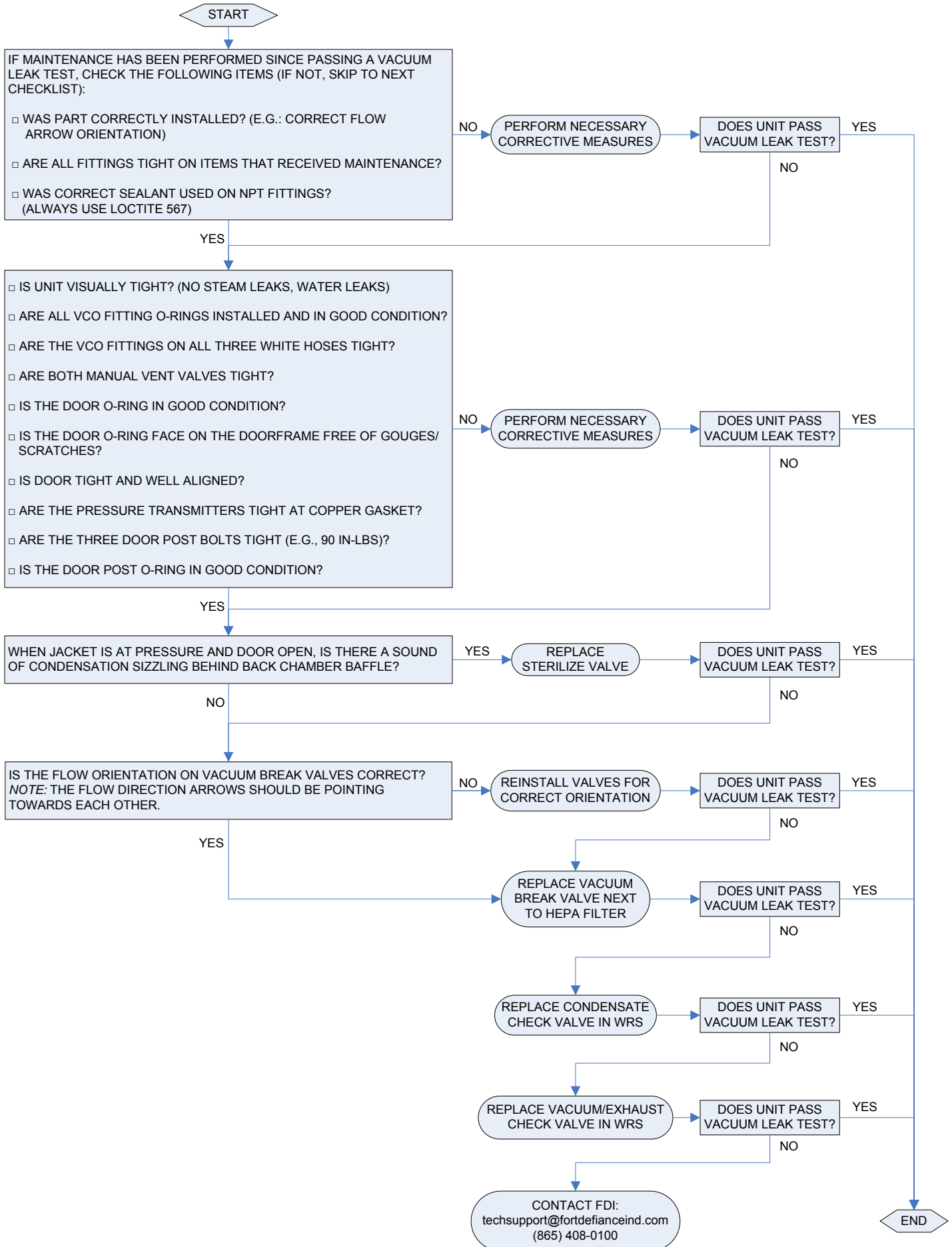
2. Look to make sure that the lip seals on the bearings are positioned properly in their grooves. Correct if necessary. As the bearings are turned, the grooves should appear wet with oil but have no visible grease present.

3. Recheck the snap ring on the large bearing end. It should be firmly in place, and no axial motion should result from gentle tapping on either end of the shaft. (Use a soft mallet so shaft surfaces are not damaged.)

4. No adjustments are possible or required. Proceed with the appropriate pump end assembly operations. Refer to Section 5 SERVICE - PUMP ENDS (Final testing is done after the pump end is in place.)

A.5 Vacuum Leak Test Troubleshooting Guide

VACUUM LEAK TEST TROUBLESHOOTING GUIDE



A.6 Suggested Maximum Values of Contaminants in Feed Water

Contaminant	Value
Residue on Evaporation	≤ 10 mg/L
Silicate	≤ 1 mg/L
Iron	≤ 0.2 mg/L
Cadmium	≤ 0.005 mg/L
Lead	≤ 0.05 mg/L
Rest of heavy metals except Iron, Cadmium, Lead	≤ 0.1 mg/L
Chloride	≤ 0.5 mg/L
Free Chlorine	≥ 0.2 mg/L
Phosphate	≤ 0.5 mg/L
Conductivity	≤ 5 µS/cm
pH (20°C, 68°F) Value	5 – 7.5
Appearance	Colorless; clean without sediment
Hardness	≤ 10 mg/L
Total Dissolved Solids (TDS)	≤ 50 ppm
<p>NOTE:</p> <ol style="list-style-type: none"> 1. Reference Section 2.5 Water Supply Quality. It is the responsibility of the user to supply feedwater that meets FDA bottled water criteria. 2. Reference Section 3.4 Operational Checklists, Testing Total Dissolved Solids (TDS), FDA-Required Water Changeout, and Testing Free Chlorine Level. It is the responsibility of the user to maintain feedwater quality by performing necessary maintenance on the SWS. 3. 1 mg/L is equal to 1 ppm (parts per million) 	

A.7 LIMITED WARRANTY

Fort Defiance Industries LLC ("FDI") warrants to the original retail purchaser that it will repair or replace components of the P2131 Automated Field Steam Sterilizer ("P2131 Sterilizer") manufactured by FDI (except for components not warranted under "Exclusions") that are defective in material or workmanship under normal use and service. FDI's obligation under this warranty is limited to the repair or replacement, at FDI's option, of the applicable components.

In cases where return of the P2131 Sterilizer for repair is not practical, FDI may, at its sole discretion, authorize in writing repair of the unit by trained technicians. In such circumstances, FDI will furnish at the place of delivery the material or parts, and the instructions required to successfully accomplish the repair.

This limited warranty shall only apply to defects that are reported to FDI within the applicable warranty period and which, upon assessment by FDI, prove to be defective. This warranty extends only to the first retail purchaser of a P2131 Sterilizer and is not transferable or assignable.

This warranty shall not limit the Customer's rights under any inspection clauses in relation to latent defects, fraud, or gross mistakes that amount to fraud. This warranty applies notwithstanding inspection and acceptance or other clauses or terms of this contract.

APPLICABLE WARRANTY PERIOD

The applicable warranty period measured from the date of delivery to the original purchaser (whether wholesale/resale or retail) shall be one (1) year.

OBTAINING WARRANTY SERVICE

FDI may be contacted for warranty service inquiries or issues via phone at 865-408-0100 or by email at techsupport@fortdefianceind.com.

EXCLUSIONS

This warranty does not cover, and FDI shall not be liable for, the following:

1. Defects, damage or other conditions caused, in whole or in part, by misuse, abuse, negligence, tampering, alteration, accident, damage during transport, or failure to seek and obtain repair or replacement in a timely manner;
2. P2131 Sterilizers which are not installed, qualified, used, and properly cleaned and maintained as required in the P2131 "Technical Manual";
3. Components considered to be of a consumable nature (e.g., O-rings, water test strips, filters) or components that will require replacement per the maintenance schedule;
4. Parts and accessories not purchased through FDI, nor product failure or damage associated with parts not purchased through FDI;
5. Charges by anyone for adjustments, repairs, replacement parts, installation or other work performed upon or in connection with such products which are not expressly authorized in writing in advance by FDI;
6. Costs and expenses of routine maintenance and cleaning; and
7. Representations and warranties made by any person or entity other than FDI.

EXCLUSIVE REMEDY; CONSEQUENTIAL DAMAGES DISCLAIMER

FDI'S ONLY OBLIGATION UNDER THIS WARRANTY IS THE REPAIR OR REPLACEMENT OF DEFECTIVE PARTS. FDI SHALL NOT BE LIABLE FOR AND HEREBY DISCLAIMS ANY DIRECT, SPECIAL, INDIRECT, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES OR DELAYS, INCLUDING, BUT NOT LIMITED TO, DAMAGES FOR LOSS OF PROFITS OR INCOME, LOSS OF USE, DOWNTIME, COVERAGE OF AN EMPLOYEE OR INDEPENDENT CONTRACTOR WAGES, PAYMENTS AND BENEFITS.

WARRANTY DISCLAIMER

THIS WARRANTY IS FDI'S ONLY WARRANTY AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED. FDI MAKES NO IMPLIED WARRANTIES OF ANY KIND INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. THIS WARRANTY IS LIMITED TO THE REPAIR OR REPLACEMENT OF DEFECTIVE PARTS. ANY LIABILITY IS EXPRESSLY LIMITED TO AN AMOUNT EQUAL TO THE PURCHASE PRICE PAID, AND ALL CLAIMS FOR SPECIAL, INCIDENTAL AND CONSEQUENTIAL DAMAGES ARE HEREBY EXCLUDED. SOME STATES OR COUNTRIES DO NOT ALLOW EXCLUSIONS OF INCIDENTAL OR CONSEQUENTIAL DAMAGES AND/OR LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, SO THE ABOVE EXCLUSIONS AND LIMITATIONS MAY NOT APPLY TO YOU. THIS LIMITED WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE OTHER RIGHTS THAT VARY FROM STATE TO STATE OR COUNTRY TO COUNTRY.

STATUTE OF LIMITATIONS

No action may be brought against FDI for breach of this limited warranty, an implied warranty, if any, or for any other claim arising out of or relating to the P2131 Sterilizer, more than ninety (90) days following expiration of the limited warranty period.